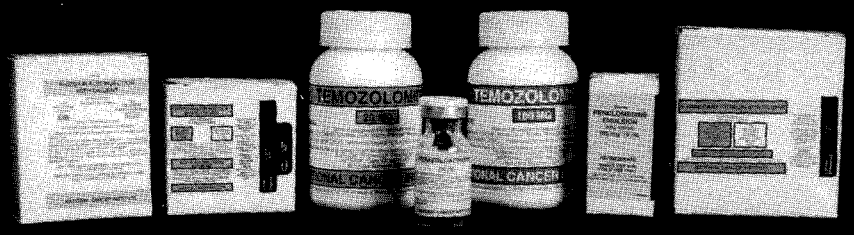
1994

NCI Investigational Drugs



Pharmaceutical Data

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES
Public Health Service
National Institutes of Health

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COVER

The inset on the cover is a representation of the temozolomide molecule generated with the Hyperchem computer molecular modeling program which depicts bonding and arrangement of electrons. The background for the cover is a photograph of crystals of the same drug. The graphics were generated respectively by Dr. E.M. Bellot of Pharm-Eco Laboratories and Mr. P.C. Reiman of the University of Iowa.

PREFACE

NCI Investigational Drugs - Pharmaceutical Data is a periodical publication prepared by the Pharmaceutical Resources Branch of the Developmental Therapeutics Program, Division of Cancer Treatment, National Cancer Institute. Special thanks due are to **James W. Wilson III, R.Ph.**, who assumed major responsibility for the preparation of the current volume prior to assuming a position with the FDA. Thanks are also owed to **Wayne E. Jackson** for his exceptional efforts in facilitating the publication of this volume. Much of the data presented in the current volume has been generated by National Cancer Institute's contractors who manufacture the dosage forms described in the book, provide required analytical services and perform shelf life surveillance studies. Their cooperation and assistance is very much appreciated.

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Copies of this publication may be requested by writing to the following address:

Pharmaceutical Resources Branch
National Cancer Institute
Executive Plaza North, Suite 818
Bethesda, MD 20892

Phone: (301) 496-8780
FAX: (301) 496-8333

Clinical drug supplies should be ordered via the appropriate mechanism from the Pharmaceutical Management Branch of the Cancer Therapy Evaluation Program, National Cancer Institute.

Phone: (301) 496-5725

INTRODUCTION

NCI Investigational Drugs - Pharmaceutical Data is designed to provide product information to health care practitioners who use investigational drug products under IND's sponsored by the Division of Cancer Treatment, National Cancer Institute, for clinical trials. Monographs are presented on investigational agents currently being manufactured by the Division of Cancer Treatment (DCT). Products distributed by the NCI which are commercially available in the United States are not included because the necessary pharmaceutical information is provided in the accompanying package insert. Additionally, more comprehensive information on the investigational drugs may be found in the clinical brochure available for each drug.

The Pharmaceutical Management Branch (PMB) of the Cancer Therapy Evaluation Program (CTEP) has taken over control of non-commercial investigational drug "gift" supplies. Monographs for these supplies are no longer included in this publication. All inquiries for investigational drug supplies, expiration dating, and general information are now screened through PMB (301-496-5725). The Pharmaceutical Resources Branch provides PMB with the information on DCT manufactured drugs to allow the practitioners the convenience of a central source for all drug information questions within the National Cancer Institute.

GENERAL INFORMATION

Product information is presented in a uniform manner. The standardized format begins with the drug's labeled name as the monograph title. When a United States Adopted Name (USAN) is available, it is generally used. Otherwise, the name most commonly applied to the agent, or in some cases the chemical name, may be used. Other identification data presented include the structural formula, CAS registry number, chemical name, any common names other than those previously listed, the molecular formula and the molecular weight.

The composition and packaging of the investigational dosage forms are then described. Descriptive terminology for parenteral products (e.g. "Sterile.....", "..... for Injection") as defined in the official United States Pharmacopeia is utilized.

NSC Numbers:

Each investigational compound studied by the NCI is assigned a unique number. This universally recognized identification number is called the "NSC" number, which refers to the former Cancer Chemotherapy National Service Center. The NCI maintains its files and data for each compound based on its assigned NSC number. When information is requested on a particular NCI compound, use of the NSC number will facilitate a response and assure that both the requestor and NCI are referring to the same compound. **NSC numbers for special diluents have been added where appropriate.**

Stability and Storage:

Recommended storage conditions for the intact dosage forms are presented in each monograph. For new products, the

recommendations are frequently based on accelerated shelf-life studies at elevated temperatures. Each new lot of investigational products manufactured by a National Cancer Institute is placed on a shelf-life surveillance study. Generally, each lot is studied for five years in the freezer (-10 °C) and recommended storage conditions. Elevated temperatures are included as appropriate. The NCI receives updated stability data every three months for the first year, every six months for the second year and yearly thereafter.

Many of the product monographs in this book include stability data for temperatures higher than the recommended storage condition. These data are provided to allow decisions on whether to use products which may have inadvertently been stored above the labeled temperature for short periods of time (e.g. a product which is labeled for refrigerated storage which is left at room temperature for a day or two).

Shipping:

Storage information is provided on the label. Occasionally, product labeling requires refrigeration, but the product is shipped without ice. These products are stable for short periods of time at room temperature, but still must be stored under refrigeration upon receipt.

Expiration Dating:

Older products carry an expiration date placed on the label, which is based on real-time stability studies. The drug may be used through the end of the month specified.

Newer drugs will carry only the manufacturing date; these drugs are undergoing stability evaluation but do not yet have an

established expiration date. The year that a drug was manufactured by a National Cancer Institute contractor can also be determined from the first two digits of the lot number (e.g. BV-87-301 and UI-90-202 were manufactured in 1987 and 1990, respectively). Any expired drug should be returned to the NCI Clinical Drug Repository along with a completed Return Drug Form.

Preparation Information:

The recommended constitution and dilution directions are based on formulation and solution stability studies performed on each drug. 0.9% Sodium Chloride Injection, USP, 5% Dextrose Injection, USP, or 5% Dextrose in 0.45% Sodium Chloride Injection, USP, the most common infusion vehicles, are usually selected for solution compatibility studies. The omission of other vehicles does not imply incompatibility. The solution stability data which have been developed are presented.

Infrequently, the formulation of a product is changed or a new vial size is made available in between editions of this book. Information in these monographs should not be used as a substitute for the preparation instructions on the label of the product.

Compatibility:

Compatibility of the investigational agents with other drugs or with antibacterial preservatives is not usually evaluated. Investigational agents manufactured by the NCI are designed as single-use dosage forms and admixture with other agents is, in general, not recommended. Compatibility studies of selected investigational agents in plastic are currently being conducted by NCI contractors.

Proper Handling and Disposal of Anti-Cancer Drugs:

The potential risks to individuals working with antineoplastic drugs have been the subject of much interest and concern in the health care community. Procedures for proper handling and disposal of anti-cancer drugs should be considered. Several guidelines on this subject have been published to assist practitioners who prepare and administer antineoplastic drugs in establishing a program of procedures designed to minimize inadvertent exposure to these agents (1-3). In addition, a videotape entitled "Safe Handling of Cytotoxic and Hazardous Drugs", 1990 edition, is available from the American Society of Hospital Pharmacists and may be used in training staff members. Although the nature and extent of any risks that might exist are uncertain, practitioners are encouraged to implement a program that will minimize their level of exposure.

Material Safety Data Sheets:

There have been several recent changes in the Hazard Communication Standard. The Hazard Communication Standard final rule was published August 24, 1987 and required that chemical manufacturers, importers, and distributors ensure that Material Safety Data Sheets (MSDS's) are provided with the next shipment of hazardous chemicals to non-manufacturing employers or distributors after September 23, 1987 (Federal Register 52:31852-31886, 1987). This revised standard exempted "drugs when they are solid, and in final form for direct administration to the patient (i.e., pills or tablets)".

Subsequently the final rule was amended December 4, 1987 (Federal Register 52: 46075-46080) to exempt any drug regulated by the FDA in the non-manufacturing sector from the requirement to supply MSDS's.

The exemption attempts to avoid duplication of paperwork because the Food and Drug Administration requires the transmittal of detailed information from the manufacturer in the form of package inserts and labels. Investigational drugs use clinical brochures as a substitute for the package insert.

Clinical brochures should be available on the clinical drugs at your institution for personnel handling and administering these antitumor agents, please request them from:

Pharmaceutical Management Branch
Cancer Therapy Evaluation Program
Division of Cancer Treatment
National Cancer Institute
Room 804, Executive Plaza North
Bethesda, Maryland 20892

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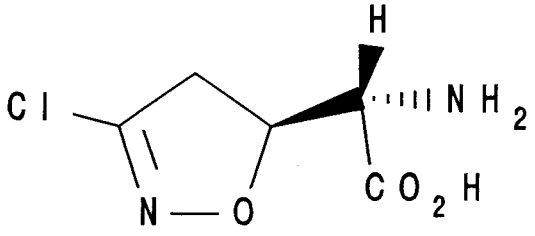
ACIVICIN

NSC - 163501

Acivicin is currently available from both the National Cancer Institute and from the Upjohn Company of Kalamazoo, Michigan for clinical trials sponsored by the Division of Cancer Treatment, National Cancer Institute. Information relevant to both products is provided below.



Chemical Name: α-Amino-3-chloro-4,5-dihydro-5-isoxazoleacetic acid, [S-(R*,R*)]-

Other Names: AT-125, U-42126, Acivicin (USAN)

CAS Registry Number: 42228-92-2

Molecular Formula: $C_5H_7ClN_2O_3$ **M.W.**: 178.6

Upjohn's Product:

How Supplied: For injection, 25 mg, vial: supplied as a lyophilized powder with 39.45 mg of mannitol, USP, and 24 mg of citric acid in 10 mL flint vials.

Solution Preparation: 25 mg/vial: When constituted with 5 mL of Sterile Water for Injection, USP, each milliliter contains 5 mg of acivicin, 7.89 mg of mannitol, USP, 4.8 mg of citric acid and sodium hydroxide to adjust the pH to approximately 5.2.

Storage: Store the intact vials at room temperature.

NCI's Product:

How Supplied: For injection, 25 mg, vial: supplied as a lyophilized powder with 25 mg of mannitol, USP in 10 mL flint vials.

Preparation: When constituted with 5 mL of Bacteriostatic Sodium Chloride Injection, USP, containing benzyl alcohol, the resulting solution contains 5 mg/mL of acivicin, and 5 mg/mL of mannitol, USP, at pH 3.5-6.5.

Storage: Store the intact vials at room temperature.

Stability: Intact vials are stable for 5 years at room temperature (22-25 °C). Intact vials are stable for at least one year when stored at elevated temperature (50 °C).

When constituted as directed, the solution exhibits no decomposition in 48 hours at room temperature (22-25 °C) or in 7 days under refrigeration (2-8 °C). Use within six hours is recommended.

> **NOTE:** Acivicin solutions exhibit very fine particles and/or very light haze under high intensity light. The particulate burden is very low, and formulated lots have met USP criteria for particulate matter. The lots are essentially free of visible particulate matter. Nevertheless, as a precaution, it is recommended that the constituted solution be filtered through a 0.22 μ filter prior to injection. Filtration does not reduce the drug content.

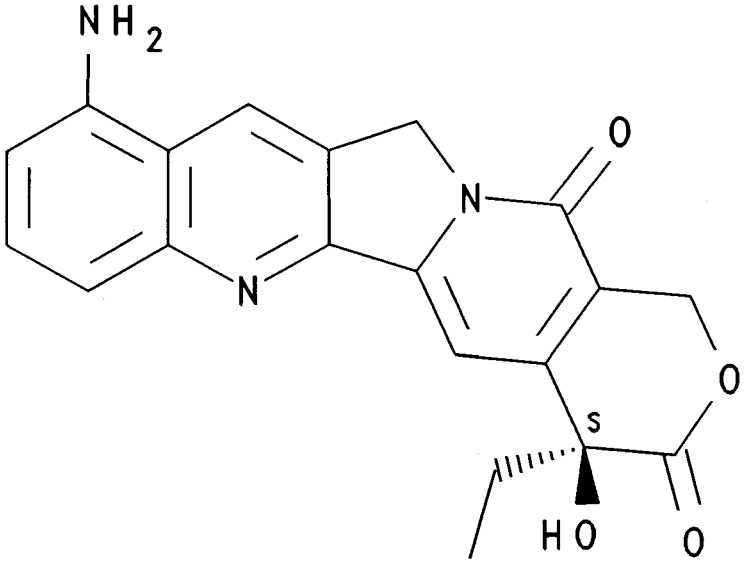
Further dilution to a concentration of 0.05 mg/mL in 5% Dextrose in 0.9% Sodium Chloride Injection, USP results in a solution which exhibits no decomposition in 48 hours at room temperature.

A 10 mg/mL solution of acivicin in amino acid injection (Aminosyn®, Abbott) showed no physical or chemical changes over a two-week observation period.

Route of Administration: Intravenous

9-AMINOCAMPTOTHECIN WITH DILUENT

NSC - 603071



Chemical Name: 9-Amino-20-(S)-camptothecin

Other Names: 9-AC

CAS Registry Number: 91421-43-1

Molecular Formula: $C_{20}H_{17}N_3O_4$ **M.W.:** 363.4

How Supplied: **NSC - 603071** Injection, 5 mg, ampule: 5 mg/mL concentrate, 1 mL, in dimethylacetamide, 1 mL/amber ampule.

Special Diluent: **NSC - 651935** Vial: Polyethylene Glycol 400, 51%, with 0.01 Molar Phosphoric Acid Buffer, 49%, 49 mL/amber vial.

Solution Preparation: Add one milliliter of the 9-amino-camptothecin /dimethylacetamide concentrate (use a glass syringe) to the amber vial containing 49 milliliters of special diluent.

The resulting mixture contains 100 micrograms of 9-aminocamptothecin per milliliter in a 2% dimethylacetamide (v/v), 50% polyethylene glycol 400 (v/v), and 48% 0.01 M phosphoric acid (v/v) solution, 50 mL per vial. Filter the final solution through a 5 micron filter. Use within 28 hours.

Note: Contact of the undiluted 9-aminocamptothecin/ dimethylacetamide concentrate with plastic items, including filters and syringes, should be avoided.

Further dilution of the 100 mcg/mL solution with 0.9% Sodium Chloride Injection must be targeted to a concentration of $\leq$ one microgram/mL as precipitation will occur at higher concentrations. Dilutions containing 0.1 to 1 mcg/mL of 9-aminocamptothecin in 0.9% Sodium Chloride Injection are stable for 28 hours. Those in 5% Dextrose Injection are less stable; this should **not** be used. These solutions may be prepared in PVC or polyolefin containers.

Caution: 9-aminocamptothecin is intended for appropriate syringe pump administration only. The drug is **not compatible** with standard infusion fluids and therefore cannot be further diluted (except as noted in the previous paragraph) nor can it be piggybacked into an existing I.V. line port. Additional special diluent is available to facilitate larger doses and to flush central venous catheters to displace any aqueous solution present.

Storage: Store the intact ampules under refrigeration (2-8 °C).

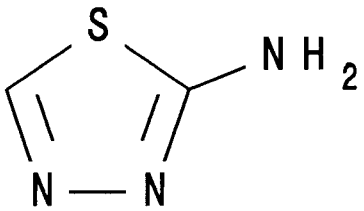
Stability: Shelf-life surveillance of the ampules and vials is ongoing.

Constitution as recommended results in a solution which is chemically and physically stable in the amber diluent vial for at least 28 hours stored at refrigerated temperature (2-8°C).

Route of Administration: Intravenous

2-AMINO-1,3,4-THIADIAZOLE

NSC - 4728



Chemical Name: 1,3,4-Thiadiazol-2-amine, 2-Amino-1,3,4-Thiadiazole

Other Name: ATDA

CAS Registry Number: 4005-51-0

Molecular Formula: $C_2H_3N_3S$ **M.W.:** 101.1

How Supplied: Sterile, 200 mg, vial: supplied as a lyophilized powder in 30 mL flint vials.

Solution Preparation: 200 mg/vial: When constituted with 19.9 mL of Sterile Water for Injection, USP, 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP, each milliliter contains 10 mg of 2-amino-1,3,4-thiadiazole. The pH of the constituted solution is 5.5 to 7.0.

Storage: Store the intact vials at room temperature.

Stability: The intact vials are stable for 5 years at room temperature (22-25 °C), and at least one year at elevated temperature (50 °C).

Constitution as recommended results in a solution which is chemically stable for at least 72 hours at room temperature. Normal room light does not affect the stability of the constituted solution.

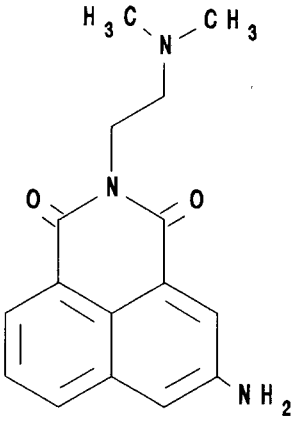
Further dilution of the constituted solution with 5% Dextrose Injection, USP, 5% Dextrose in 0.9% Sodium Chloride Injection, USP, or 0.9% Sodium Chloride Injection, USP, does not alter solution stability.

> **CAUTION**: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

AMONAFIDE

NSC - 308847



Chemical Name: 5-Amino-2-[2-(dimethylamino)ethyl]-1H-benz[de]isoquinoline-1,3(2H)-dione

Other Names: Nafidimide, Amonafide HCl (USAN) (NSC-621093)

CAS Registry Number: 69408-81-7

Molecular Formula: $C_{16}H_{17}N_3O_2$ **M.W.**: 283.3

How Supplied: Sterile, 500 mg (as the base), vial: supplied as a yellow to orange or red-orange lyophilized powder with sodium hydroxide to adjust pH in 30 mL flint vials.

Solution Preparation: 500 mg/vial: Constitution with 9.6 mL of Sterile Water for Injection, USP, or 0.9% Sodium Chloride Injection, USP, results in a solution containing 50 mg/mL of amonafide with sodium hydroxide to adjust to pH 5 to 7. The constituted solution may vary in color from yellow to red-orange or red.

Storage: Store the intact vials under refrigeration (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. Intact vials are stable for at least 3 years at room temperature (22-25 °C) and under refrigeration (2-8 °C). The intact vials are stable for at least one year at elevated temperature (50 °C).

Amonafide is stable in aqueous phosphate-buffered solutions over a pH range of 5.4 to 9.4 exhibiting little or no decomposition over 8 hours at 90 °C. However, at lower pH values increased rates of decomposition occur.

When constituted as directed with Sterile Water for Injection, USP, or 0.9% Chloride Injection, USP, amonafide solutions exhibit no decomposition over 14 days at room temperature or under refrigeration.

Further dilution to a concentration of 0.25 mg/mL in 0.9% Sodium Chloride Injection, USP, in glass or PVC containers results in a solution which exhibits no decomposition over 14 days of storage at room temperature or under refrigeration.

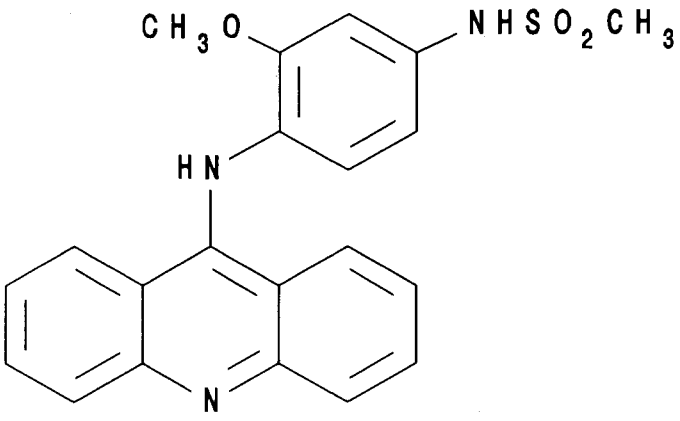
Note: Amonafide is very unstable in dextrose-containing solutions. Approximately 25 to 35% decomposition occurs over 24 hours at room temperature in 5% Dextrose Injection, USP, 5% Dextrose in 0.9% Sodium Chloride Injection, USP, and 5% Dextrose in 0.45% Sodium Chloride Injection, USP. The dextrose content may be catalyzing the degradation.

CAUTION: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

AMSACRINE

NSC - 249992



Chemical Name: N-[4-(9-Acridinylamino)- 3-methoxyphenyl]-methanesulfonamide

Other Names: m-AMSA, acridinyl anisidide, methanesulfon-m-anisidide, 4'-(9-acridinylamino)-, Amsacrine (USAN)

CAS Registry Number; 51264-14-3

Molecular Formula: $C_{21}H_{19}N_3O_3S$ **M.W.:** 393.5

How supplied: Amsacrine is available in a duopack containing two sterile liquids that must be aseptically combined prior to use, forming what is termed the "combined solution".

Each duopack contains the following:

NSC - 249992: A 2 mL flint ampule containing 1.5 mL of a 50 mg/mL solution of amsacrine (75 mg total) in anhydrous N,N-dimethylacetamide (DMA).

NSC - 367919: A 20 mL amber vial containing 13.5 mL of 0.0353 M L-lactic acid diluent.

Solution preparation:
Aseptically add 1.5 mL of the contents of the ampule of amsacrine, 50 mg/mL, to the vial containing 13.5 mL of 0.0353 M L-lactic acid. The resulting orange-red solution contains 5 mg/mL of amsacrine in 10% v/v DMA and 0.0318 M L-lactic acid.

> **NOTE:** Contact of the undiluted amsacrine solution with plastic items, including filters and syringes, should be avoided because of the concentrated N,N-dimethylacetamide solvent content. The use of glass syringes is recommended.

> **CAUTION:** Avoid direct contact of amsacrine solutions with skin or mucous membranes due to possible skin sensitization.

Storage: Store the packages at room temperature (22-25 °C).

Stability: The intact drug and diluent bear a "do not use after" date.

The "combined solution" is physically and chemically stable for at least 48 hours at room temperature (22-25 °C) under ambient light.

The "combined solution" may be further diluted with 500 mL of 5% Dextrose Injection, USP, and is physically and chemically stable for at least 48 hours at room temperature (22-25 °C) under ambient lighting.

Addition of the "combined solution" to 500 mL of 5% Dextrose Injection, USP, containing 1 mEq of sodium bicarbonate results in an admixture which has been found to be chemically stable for at least 96 hours at room temperature.

> **NOTE:** The hydrochloride salt of amsacrine is poorly water soluble. As a result, the "combined solution" is physically incompatible with Sodium Chloride Injection, USP, and other chloride-containing solutions. Admixture with these solutions may result in precipitation.

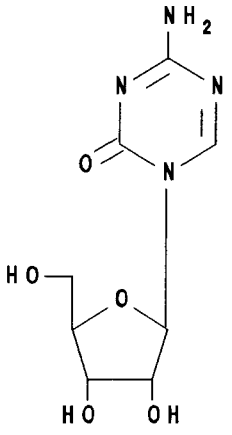
Evacuated flasks may contain a small amount of chloride-containing solution from the manufacturing process. This residual chloride ion has been sufficient to cause precipitation when amsacrine solutions have been prepared in evacuated flasks.

> **CAUTION**: These single-use solutions do not contain antibacterial preservatives. Therefore, it is advised that the vials be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

AZACITIDINE

NSC - 102816



Chemical Name: 4-Amino-1-β-D-ribofuranosyl-1,3,5-triazin-2(1H)-one

Other Names: 5-Azacytidine, Ladakamycin, Mylosar®, Azacitidine (USAN)

CAS Registry Number: 320-67-2

Molecular Formula: $C_8H_{12}N_4O_5$ **M.W.**: 244.2

How Supplied: For injection, 100 mg, vial: supplied as a white lyophilized powder with 100 mg of mannitol, USP, in 30 mL flint vials.

Solution Preparation: 100 mg/vial : When constituted with 19.9 mL of Sterile Water for Injection, USP, each milliliter contains 5 mg of azacitidine and 5 mg of mannitol, USP. The pH of the resulting solution is 6.0 to 7.5.

The constituted solution can be further diluted in Lactated Ringer's Injection, USP. The pH of this solution, at a concentration of 100 mg/500 mL, is approximately 6.4. Lactated Ringer's Injection, USP, provides optimum pH for solution stability.

Storage: Store the intact vials at refrigeration temperature (2-8 °C).

Stability: The intact vials are stable for at least 4 years at refrigeration temperature (2-8 °C). Room temperature storage (22-25 °C) has not altered the chemical potency of the product after 3 years, but because of degradation at elevated temperatures, refrigeration storage is recommended when possible.

The constituted solutions hydrolyze at room temperature and should be used within 30 minutes for delivery of maximum potency.

The mode of decomposition in the neutral pH range involves opening the triazine ring. Hydration of the 5,6-imine double bond occurs, followed by bond cleavage to yield the formyl derivative, N-(formylamidino)-N-β-D-ribofuranosylurea. Evaluations of the kinetics and mechanism of degradation of azacitidine have been reported in the literature (1,2,3,4). The pH providing optimum stability has been shown to be 6.5 to 7 (1,2,4).

Constitution as recommended with Sterile Water for Injection, USP, provides a solution with a pH value near the optimal pH. Nevertheless, the decomposition rate is rapid, and the time to 10% decomposition is very brief. The constituted solution should be used immediately or further diluted in an appropriate infusion solution and used within 30 minutes.

The stability of azacitidine 0.2 mg/mL and 2 mg/mL in several intravenous infusion solutions has been studied (5). Using a stability-indicating HPLC assay technique, azacitidine stability was found to depend, to a degree, on drug concentration and the specific infusion solution used. However, in all cases the time to 10% decomposition at 25 °C was found to be short. The results of the study are summarized in the following table:

Stability of Azacitidine in Various Infusion Fluids at 25 °C

Infusion Solution	Azacitidine Concentration (mg/mL)	Time to 10% Decompn. (hr)	Concentration after 6 hours (%)
NS			
PVC	0.2	1.6	77
Glass	0.2	1.9	79
Glass	2	2.4	82
D5W			
PVC	0.2	0.7	63
Glass	0.2	0.8	74
LR			
PVC	0.2	2.0	80
Glass	0.2	1.9	79
Glass	2	2.9	82
NR			
Glass	0.2	1.9	76
Glass	2	3.0	84

NS = 0.9% Sodium Chloride Injection, USP
D5W = 5% Dextrose Injection, USP
LR = Lactated Ringer's Injection, USP
NR = Normosol - R (pH 7.4)
PVC = Polyvinyl chloride bags

Route of Administration: Intravenous, subcutaneous

References:

1. Pithova P, Piskala J, Pitha J and Sorm F: Nucleic acid components and their analogues. LXVI. Hydrolysis of 5-azacytidine and its connection with biological activity, Coll Czech Chem Commun 30:2801-2811, 1965.

2. Notari RE and DeYoung JL: Kinetics and mechanisms of degradation of the anti-leukemic agent 5-azacytidine in aqueous solutions, J Pharm Sci 64:1148-1156, 1975.

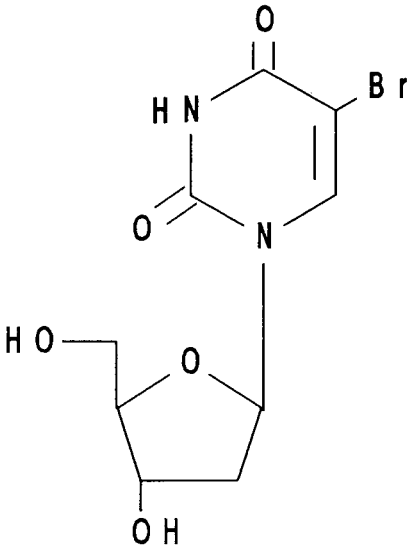
3. Beisler JA: Isolation, characterization and properties of a labile hydrolysis product of the antitumor nucleoside 5-Azacytidine, J Med Chem 21:204-208, 1978.

4. Chan KK, et al.: 5-Azacytidine hydrolysis kinetics measured by high-pressure liquid chromatography and ^{13}C - NMR spectroscopy, J Pharm Sci 68:807-812, 1979.

5. Cheung YW, Vishnuvajjala BR, Morris NL, Flora, KP, and Cradock, JC: Stability of Azacytidine in infusion fluids, Am J Hosp Pharm 41:1156-1159, 1984.

BROMODEOXYURIDINE

NSC - 38297



Chemical Name: 5-Bromo-2'-deoxyuridine

Other Names: BUdR, BrdUrd, Broxuridine (USAN)

CAS Registry Number: 59-14-3

Molecular Formula: $C_9H_{11}BrN_2O_5$ **M.W.:** 307.1

How Supplied: Sterile, 500 mg, vial: supplied as a lyophilized white crystalline material in 20 mL flint vials. Sufficient sodium hydroxide is present for pH adjustment.

Solution Preparation: 500 mg/vial : When constituted with 19.7 mL of Sterile Water for Injection, USP, or 0.9% Sodium Chloride Injection, USP, each milliliter of solution contains 25 mg of bromodeoxyuridine, pH 8.0 to 9.0.

Storage: Store the intact vials at room temperature.

Stability: The intact vials are stable for five years when stored at room temperature. Intact vials are stable for at least one year when stored at elevated temperature (50 °C).

Constitution as directed results in a solution which exhibits less than 1% decomposition during one week of storage under refrigeration (4 °C) or at room temperature (23 °C).

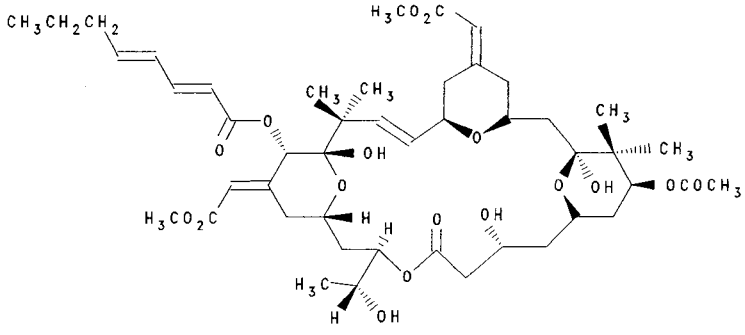
BUdR solution in PVC bags at a concentration of 0.5 mg/mL in 0.9% Sodium Chloride, USP is stable for seven days at room temperature.

> **CAUTION**: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

BRYOSTATIN
WITH PET DILUENT

NSC - 339555



Chemical Name: Bryostatin 1

Other Name: Bryostatin 1

CAS Registry Number: 83314-01-6

Molecular Formula: $C_{47}H_{68}O_{17}$ **M.W.:** 905

How Supplied:

NSC - 339555 Sterile, 0.1 mg, vial: supplied as a white lyophilized cake or powder with 5 mg of povidone, USP, in a 6 cc flint vial.

Special Diluent: NSC - 641159 Vial: PET (60/30/10) diluent, polyethylene glycol 400 (60% v/v), dehydrated ethyl alcohol (30% v/v), and polysorbate 80 (10% v/v), in a 2 cc flint vial.

> **CAUTION:** The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Solution Preparation: 0.1 mg/vial : Constitution with 1 mL of PET (60/30/10) diluent results in a solution containing 100 micrograms of bryostatin with 5 mg of povidone, USP, and polyethylene glycol 400 (60%), dehydrated ethyl alcohol (30%), and polysorbate 80 (10%), v/v.

> **CAUTION:** The primary solution must be diluted before use.

After swirling the vial to completely dissolve the contents, the resulting solution must be further diluted with nine volumes of 0.9% sodium chloride injection, USP. The resulting solution contains 10 mcg/mL of bryostatin and is stable for at least 24 hours.

CAUTION: The use of polyvinylchloride (PVC) bags is not recommended as plasticizer is leached and some limited adsorption occurs.

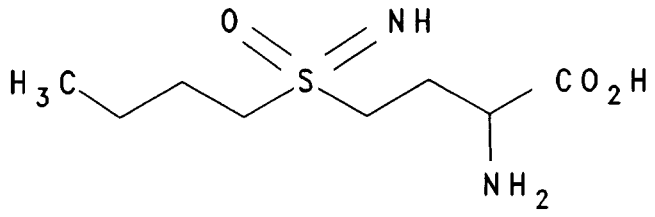
Storage: Store the intact vials under refrigeration (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing.

The diluted solution of bryostatin at a concentration of 10 mcg/mL was physically and chemically stable under normal laboratory lighting for at least 24 hours at room temperature.

Route of Administration: Intravenous

BSO
NSC - 326231



Chemical Name: 2-Amino-4-(S-butylsulfonimidoyl)-L-butanoic acid

Other Names: L-Buthionine sulfoximine

CAS Registry Number: 83730-53-4

Molecular Formula: $C_8H_{18}N_2O_3S$ **M.W.**: 222.3

How Supplied: Injection, 1 gm: 50 mg/mL, in 20 mL of Sterile Water for Injection, USP. The pH is adjusted to 7.0 to 8.0 with sodium hydroxide. The drug is supplied in a 20 mL amber vial.

Injection, 5 gm: 50 mg/mL, in 100 mL of Sterile Water for Injection, USP. The pH is adjusted to 7.0 to 8.0 with sodium hydroxide. The drug is supplied in a 100 mL amber vial.

> **NOTE:** The concentration has been changed from 100 mg/mL to 50 mg/mL to make the product isotonic and to avoid precipitation problems.

Further dilution to a concentration of 0.1 mg/mL in 0.9% sodium chloride, USP, or 5% dextrose in water, USP, in glass or plastic containers results in a solution which exhibits no decomposition over 14 days of storage at room temperature (22-25 °C).

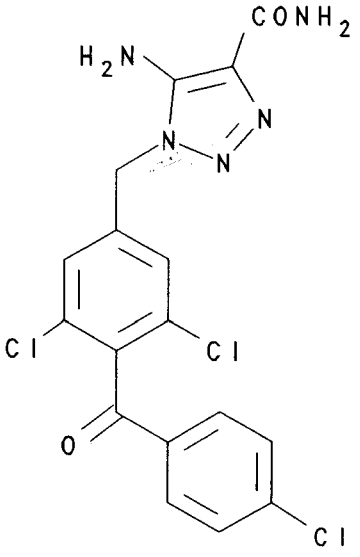
Storage: Store at room temperature (22-25 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing.

Route of Administration: Intravenous

CAI

NSC - 609974



Chemical Name: 1H-1,2,3-Triazole-4-carboxamide, 5-amino-1-[[3,5-dichloro-4-(4-chlorobenzoyl)phenyl]methyl]-

Other Names: Merck L-651,582,

CAS Registry Number: 99519-84-3

Molecular Formula: $C_{17}H_{12}N_5O_2Cl_3$ **M.W.:** 424.7

How Supplied: Oral Solution, 100 mg/mL in polyethylene glycol 400 (PEG 400)

Capsules, 15 mg: Each red soft gelatin capsule also contains polyethylene glycol 400, NF. There are 200 capsules per bottle.

Capsules, 25 mg: Each yellow soft gelatin capsule also contains polyethylene glycol 400, NF. There are 200 capsules per bottle.

Capsules, 50 mg: Each white soft gelatin capsule also contains polyethylene glycol 400, NF. There are 200 capsules per bottle.

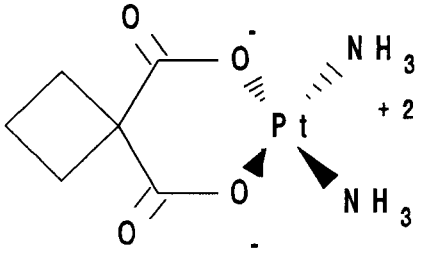
Storage: Store at room temperature

Stability: Drug in PEG 400 at 100 mg/mL is stable for at least 3 months at 50 °C. Shelf-life surveillance of bottled capsules is ongoing.

Route of Administration: Oral

CARBOPLATIN

NSC - 241240



Chemical Name: Diammine[1,1-cyclobutanedicarboxylato-(2-)-O,O']platinum (II), (SP-4-2)-

Other Names: CBDCA, Paraplatin®, JM-8, Carboplatin (USAN)

CAS Registry Number: 41575-94-4

Molecular Formula: $C_6H_{12}N_2O_4Pt$ **M.W.**: 371.3

How Supplied: For injection, 150 mg, vial: supplied as a white lyophilized powder with 150 mg of mannitol, USP, in a 20 mL amber vial.

Solution Preparation: 150 mg/vial: When constituted with 9.8 mL of Sterile Water for Injection, USP, each milliliter contains 15 mg of carboplatin and 15 mg of mannitol, USP, at pH 4.5 to 7.0.

Storage: Store the intact vials at room temperature.

Stability: The intact vials are stable for 5 years at room temperature (22-25 °C), and are stable for at least one year at elevated temperature (50 °C). Intact vials bear a three year expiration date.

When constituted as directed, the solution of carboplatin exhibits no decomposition for at least 24 hours at room temperature (22-25 °C).

Further dilution to concentrations of approximately 0.5 mg/mL and 2 mg/mL in 5% Dextrose Injection, USP, results in solutions exhibiting no decomposition for at least 24 hours at room temperature.

In a published study, at carboplatin concentrations of 0.1 and 1 mg/mL in 5% Dextrose Injection, USP, little or no decomposition occurred at 25 °C over the 6-hour study period. At 1 mg/mL in 5% Dextrose in 0.45% or 0.2% Sodium Chloride Injection, USP, little or no loss occurred in 6 hours and about 2% loss occurred in 24 hours at 25 °C. No difference was noted between glass and PVC containers (1).

However, dilution to a 1 mg/mL concentration in 0.9% Sodium Chloride Injection, USP, and 5% Dextrose in 0.9% Sodium Chloride Injection, USP, resulted in about 5% decomposition in 24 hours at 25 °C (1). These solutions are not recommended for the dilution of carboplatin because of this increased decomposition and the possible formation of the more toxic cisplatin.

CAUTION: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

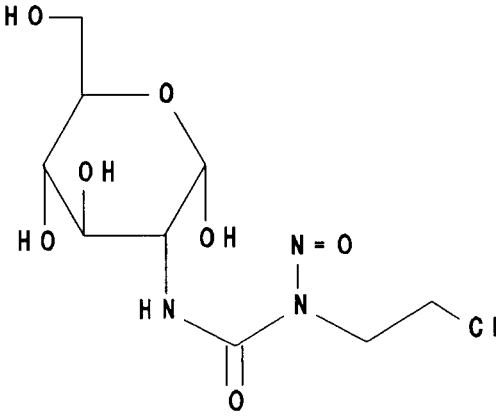
Route of Administration: Intravenous

Reference:

Cheung YW, Cradock JC, Vishnuvajjala BR, and Flora, KP: Stability of cisplatin, iproplatin, carboplatin, and tetraplatin in commonly used intravenous solutions, Am J Hosp Pharm 44:124-130, 1987.

CHLOROZOTOCIN

NSC - 178248



Chemical Name:2-[[[(2-Chloroethyl)nitrosoamino]carbonyl]-amino]-2-deoxy-D-glucopyranose

Other Name: DCNU

CAS Registry Number: 54749-90-5

Molecular Formula: $C_9H_{16}ClN_3O_7$ **M.W.**: 313.7

How Supplied: For injection, 50 mg, vial: supplied as a lyophilized powder with citric acid, 48 mg and sodium hydroxide to adjust the pH, in 10 mL amber vials.

Solution Preparation: 50 mg/vial: When constituted with 5 mL of Sterile Water for Injection, USP, or 0.9% Sodium Chloride Injection, USP, each milliliter contains 10 mg of chlorozotocin buffered to pH 3.8 to 4.2 with citric acid and sodium hydroxide.

Storage: Refrigerate the intact vials (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. Intact vials are stable for at least 4 years at room temperature (22-25 °C). Intact vials were not stable when stored at elevated temperature (50 °C) for one year. An expiration date of 24 months for intact vials stored under refrigeration (2-8 °C) is used.

Constitution as recommended results in a solution that is chemically stable for 3 hours at room temperature (22-25 °C) and 24 hours under refrigeration (2-8 °C).

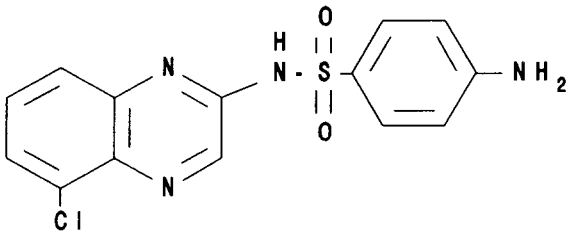
Further dilution to 0.1 mg/mL with 5% Dextrose Injection, USP, or 5% Dextrose in 0.9% Sodium Chloride Injection, USP, does not markedly affect stability.

> **CAUTION:** This single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

CHLORSULFAQUINOXALINE

NSC - 339004



Chemical Name: 4-Amino-N-[5-chloro-2-quinoxalinyl]-benzenesulfonamide

Other Names: Chloroquinoxaline Sulfonamide, CQS, Chloroquin Sulphon

CAS Registry Number: 97919-22-7

Molecular Formula: $C_{14}H_{11}ClN_4O_2S$ **M.W.**: 334.8

How Supplied: For injection, 500 mg, vial: supplied as a yellow lyophilized powder with 750 mg of meglumine (N-methylglucamine) in 20 mL amber vials.

Solution Preparation: 500 mg/vial: When constituted with 9.2 mL of Sterile Water for Injection, USP, each milliliter contains 50 mg of chlorsulfaquinoxaline and 75 mg of meglumine at pH 9.5 to 10.5.

Storage: Refrigerate the intact vials (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing.

Constitution as directed results in a solution that is physically and chemically stable for at least 14 days at 0 °C and 25 °C.

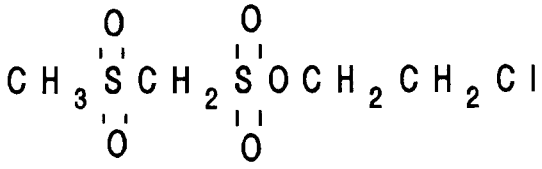
Further dilution to a concentration of 1 mg/mL in 5% Dextrose Injection, USP, or 0.9% Sodium Chloride Injection, USP, in both glass and PVC containers resulted in stable solutions exhibiting little or no decomposition in 14 days at 0 °C and 25 °C.

> **CAUTION**: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

CLOMESONE

NSC - 338947



Chemical Name: Methylsulfonylmethanesulfonic acid, 2-chlorethyl ester

CAS Registry Number: 88343-72-0

Molecular Formula: $C_4H_9ClO_5S_2$ **M.W.**: 236.7

How Supplied: For Injection, 50 mg, vial: supplied as a lyophilized powder with 200 mg of mannitol, USP in a 20 mL amber vial.

Preparation: 50 mg/vial : When constituted with 9.8 mL of 0.9% Sodium Chloride Injection, USP, each milliliter contains 5 mg of clomesone, and 20 mg of mannitol, USP, at pH 3 to 5.

Storage: Store the intact vials in the freezer (-10 to -20°C) and protected from light.

Stability: Shelf-life of the intact vials is ongoing.

Constitution as directed results in a solution that is physically and chemically stable for only two hours.

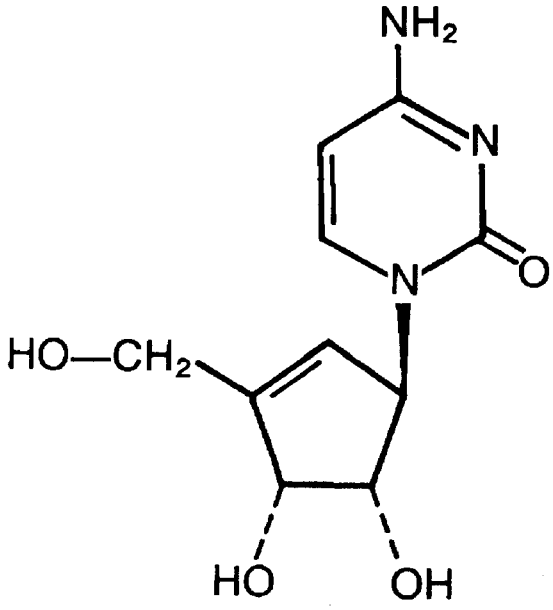
Further dilution to a concentration of 0.1 mg/mL with 0.9% Sodium Chloride Injection, USP yields a solution that is stable for only 2 hours also.

> **CAUTION**: This single-use lyophilized dosage form contains no antibacterial preservatives.
> Use within two hours after constitution.

Route of Administration: Intravenous

CYCLOPENTENYLCYTOSINE

NSC - 375575



Chemical Name:
(1*R*, 4*R*, 5*S*)-4-Amino-1-[4,5-dihydroxy-3-(hydroxymethyl)-2-cyclopenten-1-yl]-2(1*H*)-pyrimidinone

Other Names: CPE-C

CAS Registry Number: 90597-22-1

Molecular Formula: $C_{10}H_{13}N_3O_4$ **M.W.**: 239.2

How Supplied: For injection, 10 mg, vial: supplied as a lyophilized powder with mannitol, USP, 50 mg, in a 10 mL flint vial.

Solution Preparation: 10 mg/vial: When constituted with 2 mL of Sterile Water for Injection, USP, each milliliter contains 5 mg of cyclopentenylcytosine and 25 mg of mannitol, USP, at a pH of approximately 6 to 7.

Storage: Store at room temperature.

Stability: Shelf-life surveillance of the intact vials is ongoing.

Constituted solutions of CPE-C are stable at room temperature as well as at 4 °C for at least 14 days.

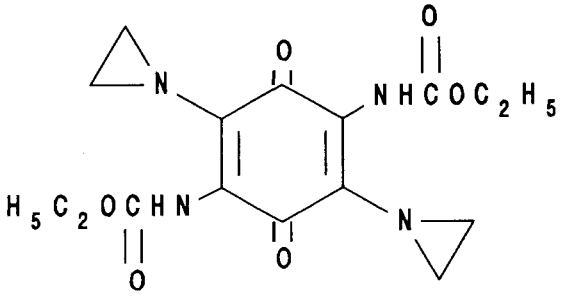
The constituted solution may be further diluted to 0.04 mg/mL with 0.9% Sodium Chloride, USP, or Dextrose 5% in Water, USP. CPE-C is stable in these solutions for at least 20 days at room temperature or refrigerated (4 °C) when stored in either glass or PVC plastic bags.

> **CAUTION**: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

DIAZIQUONE

NSC - 182986



Chemical Name: [2,5-Bis(1-aziridinyl)-3,6-dioxo-1,4-cyclohexadiene-1,4-dicarbamic acid, diethyl ester

Other Names: Aziridinyl Benzoquinone; AZQ, Diaziquone (USAN)

CAS Registry Number: 57998-68-2

Molecular Formula: $C_{16}H_{20}N_4O_6$ **M.W.**: 364.4

How Supplied: Diaziquone is provided in a tripack containing the following:

1. **NSC - 182986** A 10 mL amber vial containing in dry form 10 mg of sterile diaziquone.

2. **NSC - 3138** A 1 mL flint ampule of sterile anhydrous N,N-dimethyl-acetamide for use as a solvent.

3. **NSC - 650762** A flint vial containing 9.0 mL of sterile 0.01 M, pH 6.5 phosphate buffer (8.02 mg sodium phosphate dibasic heptahydrate and 9.04 mg sodium phosphate monobasic monohydrate in water for injection) for use as a diluent.

CAUTION: The diluent system was changed slightly to increase the N,N-dimethyl-acetamide added initially from 0.5 mL to 1.0 mL. The phosphate buffer was diminished from 9.5 mL to 9.0 mL to maintain the 1 mg/mL final concentration of AZQ.

Solution Preparation: 10 mg/vial : Completely dissolve the contents of the vial of diaziquone with one milliliter of sterile N,N-dimethylacetamide. Further dilute this solution with 9 milliliters of sterile 0.01 M, pH 6.5 phosphate buffer. The resultant solution contains 1 mg/mL of diaziquone and 5% (v/v) N,N-dimethylacetamide in pH 6.5 phosphate buffer.

NOTE: It is important that all of the diaziquone be completely in solution in the N,N-dimethylacetamide before proceeding with the addition of the buffer. Dissolution of diaziquone particles in the DMA/buffer mixture is extremely slow and most likely will not occur.

NOTE: Contact of the undiluted N,N-dimethylacetamide solvent with plastic items, including filters and syringes, should be avoided. The use of glass syringes is recommended.

Storage: Store the tripacks containing intact vials and ampules room temperature.

Stability: The product bears an expiration date.

Solutions of diaziquone are most stable in the pH range of 6.0 to 7.0. A study of diaziquone in 5% N,N-dimethylacetamide over a pH range of 3.0 to 8.0 at 25 °C yielded the following half-life results:

pH	Approx. $t_{1/2}$
3.0	1 hr
5.0	24 hr
6.0	19 days
7.0	17 days
8.0	3.5 days

Constitution of diaziquone with the two component vehicles as directed results in a solution which exhibits 3% decomposition in 24 hours and 10% decomposition in 84 hours (1) at room temperature (22-25 °C).

Further dilution to a concentration of 0.02 mg/mL in the following intravenous infusion solutions at room temperature resulted in 10% drug decomposition in the time periods indicated:

5% Dextrose Injection, USP	36 hrs
0.9% Sodium Chloride Injection, USP	44 hrs
Lactated Ringer's Injection, USP	60 hrs

CAUTION: This single-use product contains no antibacterial preservatives. Therefore, it is advised that the vials be discarded within 8 hours of initial entry.

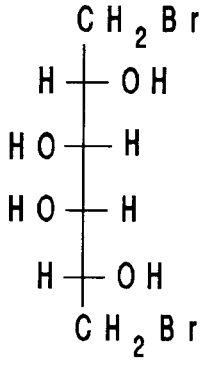
Route of Administration: Intravenous

Reference:

1. Poochikian GK and Cradock JC: 2,5-Diaziridinyl-3, 6-bis(carboethoxyamino)-1,4-benzoquinone I: Kinetics in aqueous solutions by high-performance liquid chromatography, J Pharm Sci 70: 159-162, 1981.

DIBROMODULCITOL

NSC - 104800



Chemical Name: 1,6-Dibromo-1,6-dideoxygalactitol

Other Names: DBD, Mitolactol, Elobromol, Mitolac

CAS Registry Number: 10318-26-0

Molecular Formula: $C_6H_{12}Br_2O_4$ **M.W.:** 308.0

How Supplied: Tablets, 50 mg, scored: Each white tablet also contains the inert ingredients Avicel® PH101, Talc, USP, and Sterotex®. There are 50 tablets per bottle.

Tablets, 100 mg, scored: Each white tablet also contains the inert ingredients Avicel® PH101, Talc, USP, and Sterotex®. There are 50 tablets per bottle.

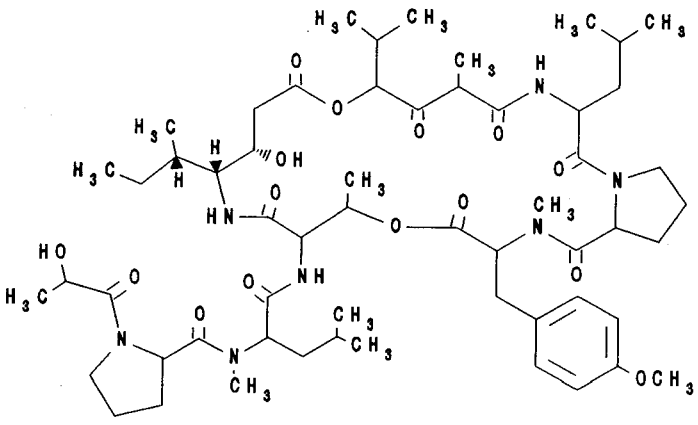
Storage: Store the tablets at room temperature.

Stability: Shelf-life surveillance of the tablets is ongoing. The tablets in intact bottles are stable for at least 4 years at room temperature (22-25 °C).

Route of Administration: Oral

DIDEMNIN B

NSC - 325319



Chemical Name: N-[1-[N-[4-[[3-Hydroxy-4-[[N-[N-[1-(2-hydroxy-1-oxopropyl)-L-prolyl]-N-methyl-L-leucyl]-L-threonyl]amino-5-methyl-1-oxoheptyl]oxy]-2,5-dimethyl-1,3-dioxohexyl]-L-leucyl]-L-prolyl]-N,O-dimethyl-L-tyrosine, ϕ-lactone

CAS Registry Number: 77327-05-0

Molecular Formula: $C_{57}H_{89}N_7O_{15}$ **M.W.:** 1112.0

How Supplied: Injection, 0.5 mg/mL, 1 mL per flint ampule in ethanol 5% (v/v), polyethoxylated castor oil (Cremophor EL®) 5% (v/v) and 0.9% Sodium Chloride Injection, USP, qs 1 mL. Ten ampules are packed per box.

Storage: Refrigerate the intact ampules (2-8 °C).

Stability: Shelf-life surveillance of the intact ampules is ongoing. The intact ampules are stable for 5 years at frozen (-10 °C) and refrigeration (2-8 °C) temperatures. Intact ampules are stable for only 6 months at room temperature (22-25 °C).

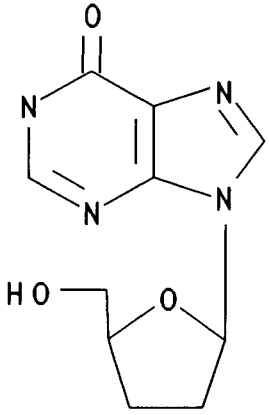
Didemnin B injection diluted to a concentration of 0.05 mg/mL (the limit of detection of the HPLC assay method) in 5% Dextrose Injection, USP, and 0.9% Sodium Chloride Injection, USP, exhibited no decomposition in 4 days at 25 °C.

Route of Administration: Intravenous

DIDEOXYINOSINE

NSC - 612049

The following information applies to the injectable dosage form of dideoxyinosine manufactured by the National Cancer Institute.



Chemical Name: 2', 3'-Dideoxyinosine

Other Names: ddI, Videx®, didanosine (USAN)

CAS Registry Number: 69655-05-6

Molecular Formula: $C_{10}H_{12}N_4O_3$ **M.W.:** 236.2

How Supplied: Sterile, 250 mg, vial: supplied as a white lyophilized powder with sodium hydroxide to adjust pH.

Solution Preparation: 250 mg/vial : When constituted with 16.5 mL of 0.9% Sodium Chloride Injection, USP, each milliliter of solution contains 15 mg of dideoxyinosine with sodium hydroxide to adjust to pH 6.0 to 8.5. Shake the vial vigorously for two to three minutes to insure complete dissolution.

Storage: Store the intact vials under refrigeration (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. Two lots of ddI were stable at room temperature (22-25 °C) for four years, and stable at elevated temperature (50 °C) for one year.

Constitution as directed results in a solution that is physically and chemically stable for at least five days at room temperature and at 37 °C. After eight hours storage at 4 °C, crystals formed in the constituted solution. The crystals redissolved with warming to ambient temperature and with vigorous shaking for about three minutes.

Further dilution to a concentration of 0.45 mg/mL in 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP, in glass, PVC, or polyolefin containers yielded the following stability results:

Percentage of Initial Dideoxyinosine[a] Remaining in Solution

Diluent	Temp (°C)	Container	Days 1	5	14
D5W[b]	25	glass	92	62	23
		PVC	76	28	4
	4	glass	97	94	89
		PVC	92	85	71
NS[c]	25	glass	97	96	93
		PVC	97	98	94
		polyolefin	103	103	96
	4	glass	100	98	99
		PVC	100	98	99

(a) Initial dideoxyinosine concentration 0.45 mg/mL.
(b) 5% Dextrose Injection, USP
(c) 0.9% Sodium Chloride Injection, USP

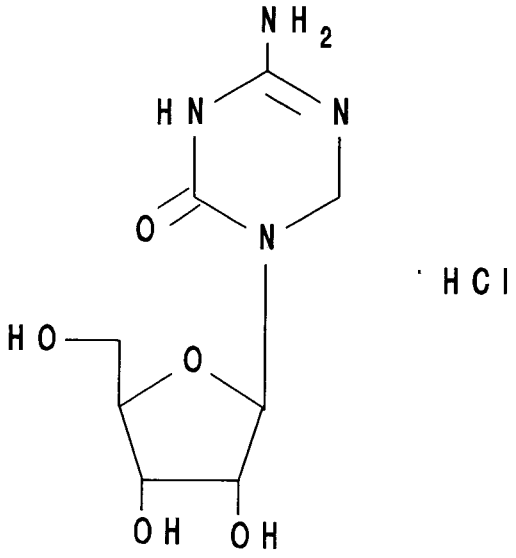
CAUTION: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Inline filtration of a 0.5 mg/mL solution in 0.9% Sodium Chloride, USP, in a PVC bag, did not cause any drug loss during a simulated four-hour infusion through a 0.22 μm filter.

Route of Administration: Intravenous

DIHYDRO-5-AZACYTIDINE

NSC - 264880



Chemical Name: 4-Amino-3,6-dihydro-1-β-D-ribofuranosyl-1,3,5-triazin-2(1H)-one, monohydrochloride

Other Names: DHAC

CAS Registry Number: 62402-31-7

Molecular Formula: $C_8H_{14}N_4O_5 \cdot HCl$ **M.W.:** 282.7

How Supplied: For Injection, 500 mg, vial: supplied as a white lyophilized powder with 300 mg of mannitol, USP, in a 20 mL flint vial.

Solution Preparation: 500 mg/vial: When constituted with 9.6 mL of Sterile Water for Injection, USP, each milliliter contains 50 mg of dihydro-5-azacytidine HCl and 30 mg of mannitol at pH 3.0 to 5.0.

Storage: Store the intact vials under refrigeration (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. The intact vials are stable for at least 4 years at room temperature (22-25 °C), at least one year at elevated temperature (50 °C).

Solutions of dihydro-5-azacytidine HCl are stable over a pH range of 3 to 8. A study of dihydro-5-azacytidine HCl 3.75 mg/mL in buffer solutions with pH values varying from 3 to 8 stored at 50 °C showed 2 to 3% decomposition in 2 days at all pH values.

When constituted as directed, dihydro-5-azacytidine HCl solutions exhibit little or no decomposition over 24 hours at room temperature.

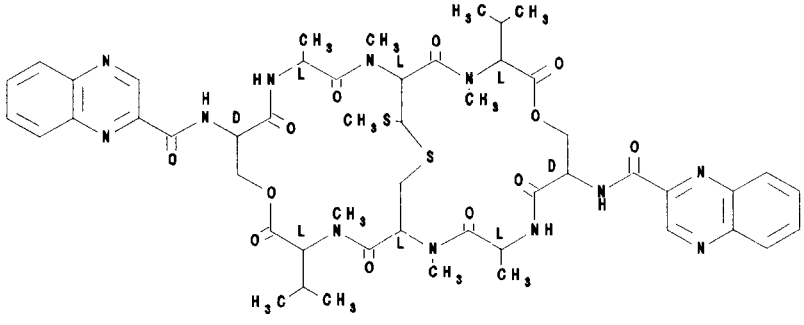
Further dilution to a concentration of 0.5 mg/mL in 5% Dextrose in 0.9% Sodium Chloride Injection, USP, and in Lactated Ringer's Injection, USP, results in solutions which exhibit 1 to 2% decomposition over 2 days at room temperature.

CAUTION: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

ECHINOMYCIN

NSC - 526417



Chemical Name: N,N'-[2,4,12,15,17,25-Hexamethyl-11,24-bis(1-methylethyl)-27-(methylthio)-3,6,10,13,16,19,23,26-octaoxo-9,22-dioxa-28-thia-2,5,12,15,18,25-hexaazabicyclo[12.12.3]nonacosane-7,20-diyl]bis-2-quinoxalinecarboxamide

Other Name: Quinomycin A

CAS Registry Number: 512-64-1

Molecular Formula: $C_{51}H_{64}N_{12}O_{12}S_2$ **M.W.:** 1101.0

How Supplied:

NSC - 526417 Sterile, 0.4 mg, vial: supplied as a white vacuum-dried film in a 3.5 mL flint vial.

NSC - 614387 Flint ampule containing 1 mL of sterile Diluent 12, composed of equal parts of polyoxyethylated castor oil (Cremophor EL®) and ethanol.

Solution Preparation: 0.4 mg/vial: Completely dissolve the contents of the vial of echinomycin with 0.2 mL of Diluent 12. After complete dissolution has occurred, add 1.8 mL of Sterile Water for Injection, USP, or 0.9% Sodium Chloride Injection, USP. The resulting solution contains 0.2 mg/mL of echinomycin. The pH of this solution is 4 to 7.

Storage: Store the intact packages in the freezer (-10 to -20 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. Two lots have been found to be stable for at least 48 months at room temperature (22-25 °C). Shelf-life surveillance studies are continuing.

Short-term storage for 14 days or less at 37 °C in 75% relative humidity does not result in measurable decomposition or physical changes to echinomycin.

When constituted as directed, the solution of echinomycin exhibits little or no decomposition for at least 8 hours both at room temperature (22-25 °C) and under refrigeration (2-8 °C).

Further dilution with 5% Dextrose in 0.9% Sodium Chloride Injection, USP, to a concentration of 0.4 mg/40 mL results in a solution exhibiting little or no decomposition for 24 hours at room temperature (both exposed to light and in the dark) or under refrigeration.

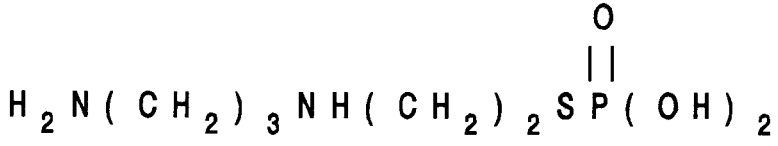
CAUTION: The single-use vial contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

CAUTION: A vacuum should be present in intact vials. Do not use unless a vacuum is present because the sterility may be compromised and increased rates of drug decomposition may occur.

Route of Administration: Intravenous

ETHIOFOS

NSC - 296961



Chemical Name: 2-[(3-Aminopropyl)amino]ethanethiol, dihydrogen phosphate (ester)

Other Names: Ethyol™; Amifostine(USAN); Gammaphos; WR-2721

CAS Registry Number: 20537-88-6

Molecular Formula: $C_5H_{15}N_2O_3PS$ **M.W.:** 214.2

How Supplied: For injection, 500 mg, vial: supplied as a lyophilized powder with 500 mg of mannitol, USP, in 10 mL amber vials.

Solution Preparation: 500 mg/vial: When constituted with 9.3 mL of Sterile Water for Injection, USP, each milliliter of solution contains 50 mg of ethiofos and 50 mg of mannitol, USP, pH 6.0 to 8.0.

Storage: Store the intact vials in the freezer (-20 to -10 °C).

Stability: Shelf-life surveillance studies are continuing. Intact vials are stable for at least 2 years when stored in the freezer (-20 to -10 °C) or at refrigeration temperature (4 °C). Intact vials are less stable when stored at room temperature.

When constituted as directed, the solution exhibits no decomposition for at least 8 hours at room temperature (20-25 °C).

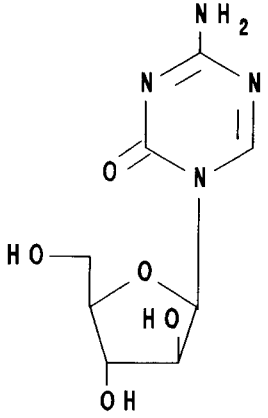
Diluted to a concentration of 10 mg/mL in 5% Dextrose Injection, USP, or 0.9% Sodium Chloride Injection, USP, ethiofos is stable for at least 24 hours at room temperature exposed to light or in the dark.

> **CAUTION:** This single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

FAZARABINE

NSC - 281272



Chemical Name: 4-Amino-1-β-D-arabinofuranosyl-1,3,5-triazin-2(1H)-one

Other Names: Ara-AC; 5-Azacytosine arabinoside, Fazarabine (USAN)

CAS Registry Number: 65886-71-7

Molecular Formula: $C_8H_{12}N_4O_5$ **M.W.:** 244.2

How Supplied: Sterile, 250 mg, vial: supplied as a white lyophilized powder in a 60 mL flint vial. Fazarabine for infusion in aqueous solutions (3 hours or less) is labeled differently from fazarabine for infusion in DMSO, but the products are identical.

Solution Preparation: The drug is prepared using one of the two following preparation methods:

1. Aqueous preparation:

Constitute the 250 mg vial with 25 mL of Sterile Water for Injection, USP, to yield a 10 mg/mL solution. Immediately further dilute the dose in a suitable quantity of Lactated Ringer's Injection, USP, to yield a fazarabine concentration of between 0.01 and 1 mg/mL. Because of fazarabine's rapid decomposition, infusions must be completed in three hours or less.

> **Note**: Older aqueous labels used 10 mL constitution volumes to give a 25 mg/mL concentration. This concentration takes up to ten minutes to achieve with vigorous shaking . Since the product is further diluted anyway the 25 mL addition of Sterile Water achieves complete solution within three minutes.

2. DMSO preparation:

Constitute the 250 mg vial with 3.5 mL of sterile 70% (v/v) dimethylsulfoxide (DMSO) NSC - 763 to yield a 70 mg/mL solution. Further dilute according to protocol instructions with additional sterile 70% DMSO to yield the appropriate fazarabine concentration. This solution is to be administered slowly into a running intravenous infusion of 5% Dextrose Injection, USP, via a side injection port using a syringe pump. A total volume of 12 mL with an infusion rate of 0.5 mL/hour is suggested for the fazarabine in 70% DMSO solution.

NOTE: It is recommended that the accuracy of the syringe pump delivery rate be verified (using sterile water for injection or other aqueous solution) prior to drug administration.

This administration approach was developed by Dr. A. J. Repta and associates at the University of Kansas. For additional information see their published article: Mojaverian P and Repta AJ: J Pharmacy Pharmacol 36: 728-733, 1984.

Storage: Store the intact vials under refrigeration (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. The intact vials are stable for at least 4 years at room temperature (22-25 °C). The intact vials are stable for at least one year when stored at elevated temperature (50 °C).

Constitution of fazarabine with 10 mL of Sterile Water for Injection, USP, and further dilution to a final concentration between 0.01 and 1 mg/mL in Lactated Ringer's Injection, USP, results in a solution which exhibits approximately 10% decomposition in three hours at room temperature. Consequently, infusion of solutions prepared in this manner should be completed within three hours of admixture.

Fazarabine constituted and further diluted with 70% DMSO is more stable. At fazarabine concentrations ranging from 2 to 70 mg/mL, the drug exhibits approximately 10% loss in 24 hours at room temperature.

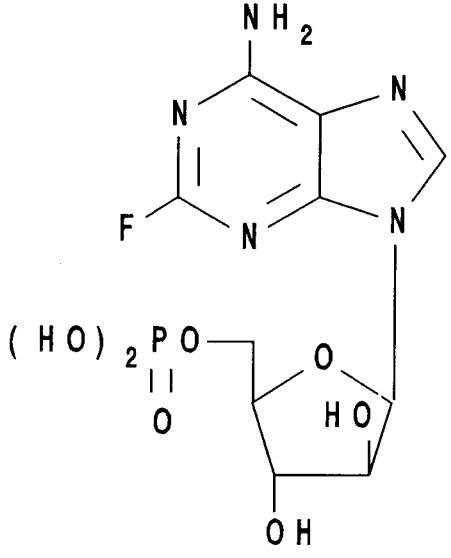
NOTE: To minimize the extraction of plasticizer from polyvinyl chloride (PVC) I.V. tubing by DMSO solvent, use of sterile microbore tubing with an inner lining of polyolefin is recommended for connecting the syringe pump to the side port of the running 5% Dextrose Injection, USP, infusion. A tubing known to be satisfactory is the Polyfin® extension set supplied by Mini Med Technologies (12744 San Fernando Road, Sylmar, CA 91342. Telephone: 800-933-3322 in California.)

Route of Administration: Intravenous

FLUDARABINE PHOSPHATE

NSC - 312887

The following information applies to the injectable dosage form of fludarabine supplied by Berlex, for clinical trials sponsored by the Division of Cancer Treatment, National Cancer Institute.



Chemical Name: 2-Fluoro-9-(5-O-phosphono-β-D-arabino-furanosyl)-9H-purin-6-amine

Other Names: Fludara™; FAMP; Fludarabine Phosphate (USAN)

2-Fluoro-Adenine Arabinoside-5-phosphate; 2-Fluoro-ARA AMP

CAS Registry Number: 75607-67-9

Molecular Formula: $C_{10}H_{13}FN_5O_7P$ **M.W.:** 401.2

How Supplied: For injection, 50 mg, vial: supplied as a white lyophilized powder with mannitol, USP, 50 mg, and sodium hydroxide to adjust pH in a 5 mL flint vial.

Solution Preparation: 50 mg/vial: When constituted with 2 mL of Sterile Water for Injection, USP, each mL of the resulting solution contains 25 mg of fludarabine phosphate, 25 mg of mannitol, USP, and sodium hydroxide to adjust to pH 6.5 to 8.5.

Storage: Store the intact vials at refrigerated temperature (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. Berlex is now conducting shelf-life evaluation of this drug.

Fludarabine phosphate is relatively stable in aqueous solution. Over a pH range of approximately 4.5 to 8 in aqueous buffer solutions stored at 65 °C, less than 4% decomposition occurred in 1 day and less than 10% occurred in 4 days. At pH 3 at 65 °C, approximately 11% decomposition occurred in one day. From this pH profile, the optimum pH was determined to be approximately 7.6.

At a concentration of 25 mg/mL in distilled water stored at room temperature (22-25 °C) in normal laboratory light, fludarabine phosphate exhibited less than 2% decomposition in 16 days.

Diluted to a concentration of 1 mg/mL in 5% Dextrose Injection, USP, or in 0.9% Sodium Chloride Injection, USP, less than 3% decomposition occurred in 16 days at room temperature (22-25 °C) under normal laboratory light.

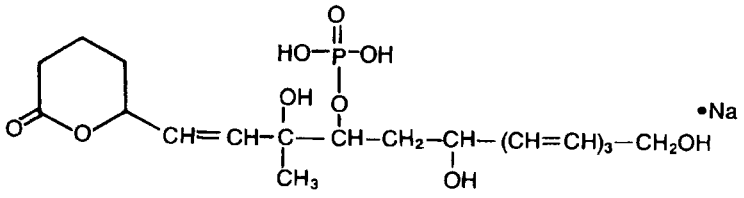
Diluted to a concentration of 0.04 mg/mL in 5% Dextrose Injection, USP, or in 0.9% Sodium Chloride Injection, USP, in glass bottles and PVC bags, little or no loss occurred in 48 hours at room temperature (22-25 °C) exposed to normal laboratory light and under refrigeration (2-8 °C).

> **CAUTION**: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

FOSTRIECIN SODIUM

NSC - 339638



Chemical Name: 5,6-dihydro-6-[3,6,13-trihydroxy-3-methyl-4-(phosphonooxy)-1,7,9,11-tridecatetraenyl]-2H-Pyran-2-one, monosodium salt

Other Names: Pyranone Phosphate; Phosphotrienin, Fostriecin Sodium (USAN)

CAS Registry Number: 87810-56-8

Molecular Formula: $C_{19}H_{26}O_9$ P . Na **M.W.**: 452.4

How Supplied: For Injection, 25 mg, prepared as an off white or pale yellow lyophilized powder with 39 mg of ascorbic acid and sodium hydroxide to adjust pH.

Solution Preparation: 25 mg/vial: When constituted with 2 mL of 0.9% Sodium Chloride Injection, USP, each millimeter contains 12.5 mg of Fostriecin and 19.5 mg of ascorbic acid with sodium hydroxide to adjust to pH 6.5 to 7.5.

Storage: The intact vials should be stored in the freezer (-10 to -20°C) and protected from light.

Stability: Shelf-life surveillance of the intact vials is ongoing.

Fostriecin exhibits maximum stability in aqueous solution in the pH range of 6.5 to 7.5. When constituted as directed, the solution exhibits no detectable decomposition in eight hours and about 4% loss in 24 hours at room temperature. Approximately 20 to 25% loss occurs after seven days of room temperature storage. When stored under refrigeration, less than 5% loss occurs in seven days.

> **CAUTION:** This single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

When diluted to a concentration of 0.05 mg/mL in 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP, for intravenous infusion, about 2 to 4% loss occurs in 24 hours at room temperature. The infusion solutions were stable for four days when stored under refrigeration at 4 °C exhibiting little or no loss.

The Fostriecin solutions were substantially less stable when stored frozen at -20°C compared to room temperature or refrigerator storage. Consequently, storage of frozen solutions of Fostriecin is not recommended. However, frozen storage of the intact vials with the drug in the dry state is required to maximize long-term stability.

Route of Administration: Intravenous

GALLIUM NITRATE

NSC - 15200

$Ga(NO_3)_3$

Chemical Name: Gallium Nitrate

Other Names: Ganite®, Gallium Nitrate (USAN)

Cas Registry Number: 13494-90-1

Molecular Formula: GaN_3O_9 **M.W.:** 256.0

How Supplied: Injection, 500 mg, vial: supplied as a 25 mg/mL solution in 20 mL flint vials. Each milliliter also contains trisodium citrate dihydrate, 28.75 mg and sodium hydroxide to adjust to pH 6.0-7.0.

Storage: Store at controlled room temperature.

Stability: The solution in intact vials is stable for at least 4 years at room temperature.

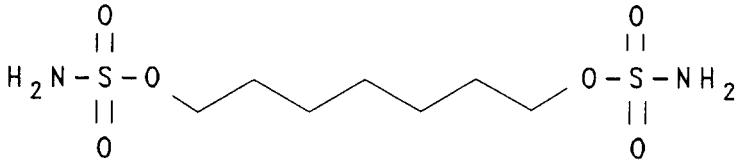
Further dilution in up to 500 mL of 5% Dextrose in 0.9% Sodium Chloride Injection, USP, results in a solution which is physically stable for at least 24 hours at room temperature.

CAUTION: Gallium nitrate solution should be administered by slow intravenous infusion. Only clear solutions should be used.

Routes of Administration: Intravenous, subcutaneous

HEPSULFAM WITH DILUENT

NSC - 329680



Chemical Name: Sulfamic Acid, 1,7-Heptanediyl ester

CAS Registry Number: 96892-57-8

Molecular Formula: $C_7H_{18}N_2O_6S_2$ **M.W.**: 290.4

How Supplied: Hepsulfam is available in a duopack containing the lyophilized drug and a sterile special diluent that must be aseptically combined prior to use, forming the "combined solution".

Each duopack contains:

NSC - 329680: One 10 mL flint vial containing 150 mg of hepsulfam.

NSC - 652019: One 5 mL flint ampule containing 5 mL of special diluent composed of ethanol 10% (v/v) and propylene glycol 40% (v/v) in pH 7.4, 0.05 M phosphate buffer.

Solution Preparation: Aseptically add 4.8 mL of the special diluent to the vial containing 150 mg of hepsulfam. The resulting solution will contain hepsulfam 30 mg/mL in ethanol 10% (v/v), propylene glycol 40% (v/v), and pH 7.4 , 0.05 M phosphate buffer. Use no other diluent for initial constitution.

Storage: Store the intact packages under refrigeration (2-8 °C).

Stability: The intact vials and diluent ampules bear a preparation date. Shelf-life evaluation is ongoing.

The "combined solution" is physically and chemically stable for at least 72 hours at room temperature (22-25 °C).

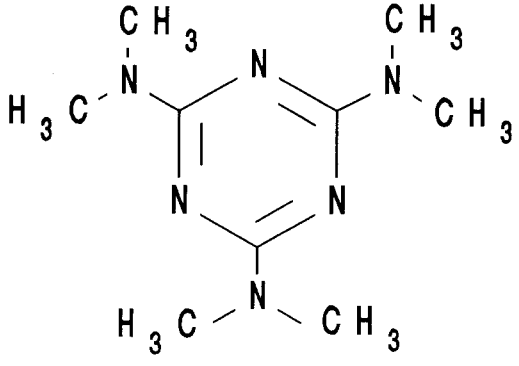
The "combined solution" may be further diluted with 5% Dextrose Injection, USP or 0.9% Sodium Chloride to a concentration of 3 mg/mL. The solution is physically and chemically stable for at least 24 hours at room temperature (22-25 °C).

> **CAUTION**: The single-use vacuum dried dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

HEXAMETHYLMELAMINE

NSC - 13875



Chemical Name: N,N,N',N',N'',N''-Hexamethyl-1,3,5-triazine-2,4,6-triamine

Other Names: HMM, Altretamine (USAN), Hexalen®

CAS Registry Number: 645-05-6

Molecular Formula: $C_9H_{18}N_6$ **M.W.:** 210.3

How Supplied: Capsules, 50 mg, with anhydrous lactose and calcium stearate.

The drug and inert ingredients are packed in a colorless, transparent, hard gelatin capsule. There are 100 capsules per bottle.

Capsules, 100 mg, with anhydrous lactose and calcium stearate. The drug and inert ingredients are packed in opaque orange- and-white, hard gelatin capsules. There are 100 capsules per bottle.

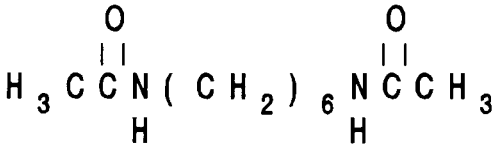
Storage: The capsules should be stored in tightly sealed bottles at room temperature. A desiccant packet is enclosed in each bottle.

Stability: Intact bottles bear a preparation date. Shelf-life evaluation is ongoing.

Route of Administration: Oral

HMBA

NSC - 95580



Chemical Name: N,N'-1,6-hexanediylbisacetamide

Other Name: Hexamethylene bisacetamide

CAS Registry Number: 3073-59-4

Molecular Formula: $C_{10}H_{20}N_2O_2$ **M.W.:** 200.3

How Supplied: Injection, 5%, 500 mL infusion bottle: Each mL of solution contains 50 mg of HMBA (25 gm total per bottle). The solution has a pH of 4.5 to 6.5. The approximate osmolality is 250 mOsm/kg of solution.

Tablets, 1 gm: Each white, scored, coated tablet also contains microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. There are 50 tablets per bottle.

Storage: The infusion bottles should be stored at controlled room temperature (15 to 30 °C). Do not refrigerate or freeze.

The tablets may also be stored at room temperature.

Stability: Shelf-life surveillance of tablets is ongoing. Tablets are stable for at least 4 years at room temperature.

Infusion: Shelf-life surveillance of the intact bottles is ongoing. Intact bottles are stable for at least four years at room temperature (22-25 °C). The bottles are stable at elevated temperature (50 °C) for one year.

> **CAUTION**: The 5% HMBA in Sterile Water for Injection should not be used unless it is sparkling clear and a vacuum is present.

The addition of other medications to 5% HMBA in Sterile Water for Injection is not advised.

Storage of 5% HMBA in PVC bags for 90 days at room temperature did not result in the leaching of significant amounts of phthalate plasticizer.

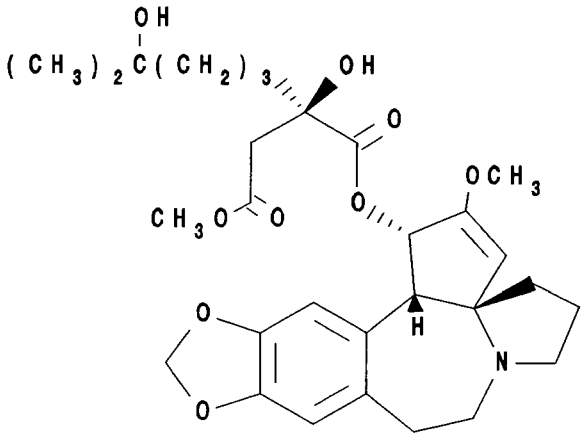
NOTE: The infusion bottle requires the use of a self-venting administration set. The use of an in-line filter does not affect the potency of this product.

Tablets: Shelf-life surveillance of the tablets in intact bottles is ongoing. One lot of tablets was found to be stable for at least 48 months at refrigeration and room temperatures. The tablets are stable for at least one year at elevated temperature (37 °C).

Routes of Administration: Intravenous, oral.

HOMOHARRINGTONINE

NSC - 141633



Chemical Name: Cephalotaxine, 4-methyl 2-hydroxy-2-(4-hydroxy- 4-methylpentyl)-butanedioate (ester), [3(R)]-

Other Name: HHT

CAS Registry Number: 26833-87-4

Molecular Formula: $C_{29}H_{39}NO_9$ **M.W.**: 545.6

How Supplied: For Injection, 10 mg, vial: The product is supplied as a lyophilized powder in 10 mL amber vials with mannitol, USP, 50 mg and hydrochloric acid to adjust pH.

Solution Preparation: Vial, 10 mg: When constituted with 4.9 mL of 0.9% Sodium Chloride Injection, USP, each milliliter contains 2 mg of homoharringtonine with 10 mg of mannitol, USP, and hydrochloric acid to adjust the pH to 3.0 to 5.0.

Storage: Store the intact vials in the refrigerator (4 to 8 °C).

Stability: Intact vials are stable for 5 years at room temperature (22-25 °C). Intact vials are stable for at least one year when stored at elevated temperature (50 °C). The vials bear a 3 year expiration date.

Constitution as recommended results in a solution which is chemically and physically stable for 96 hours at room temperature under normal fluorescent lighting.

Further dilution of the constituted solution to concentrations of 0.05 mg/mL and 0.01 mg/mL in 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP, also results in solutions which are chemically and physically stable for at least 96 hours at room temperature under normal fluorescent lighting.

> **CAUTION:** The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

HYDRAZINE SULFATE

NSC - 150014

$$H_2NNH_2 \cdot H_2SO_4$$

Chemical Name: Hydrazine, sulfate (1:1)

CAS Registry Number: 10034-93-2

Molecular Formula: $H_6N_2O_4S$ **M.W.:** 130.1

How Supplied: Capsules, 60 mg: Each pink, opaque, hard gelatin capsule also contains corn starch, N.F. and magnesium stearate. There are 100 capsules per bottle.

Identical placebo capsules containing corn starch, N.F. and magnesium stearate are also supplied. There are 100 capsules per bottle.

Storage: Store the intact bottles at room temperature.

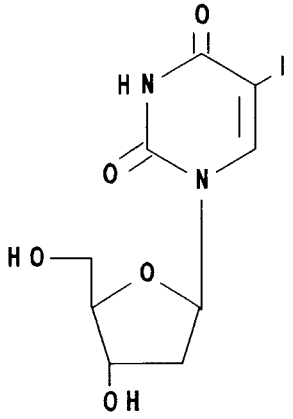
Stability: Shelf-life surveillance of the capsules in intact bottles is ongoing. The capsules should be kept in intact bottles with the desiccant packet enclosed in each bottle.

Route of Administration: Oral

IODODEOXYURIDINE

NSC - 39661

The following information applies to the investigational dosage form of iododeoxyuridine. For information on the commercially available dosage form, consult the package insert supplied by the manufacturer.



Chemical Name: 5-Iodo-2'-deoxyuridine

Other Names: IDU, IUdR, IdUrd, Idoxuridine (USAN)

CAS Registry Number: 54-42-2

Molecular Formula: $C_9H_{11}IN_2O_5$ **M.W.:** 354.1

How Supplied: Sterile, 200 mg, vial: supplied as a white lyophilized powder with sodium hydroxide to adjust pH in 30 mL amber vials.

Solution Preparation: 200 mg/vial: When constituted with 10 mL of Sterile Water for Injection, USP, each milliliter contains iododeoxyuridine 20 mg with sodium hydroxide to adjust to pH 9 to 10.

Storage: Store the intact vials at room temperature.

Stability: Intact vials are stable for five years when stored at room temperature and are stable for at least one year when stored at elevated temperatures (50 °C).

At a concentration of 20 mg/mL in distilled water, iododeoxyuridine is stable exhibiting less than 2% decomposition in 2 days at room temperature (22-25 °C). Particulate matter was observed in the solution after 2 days.

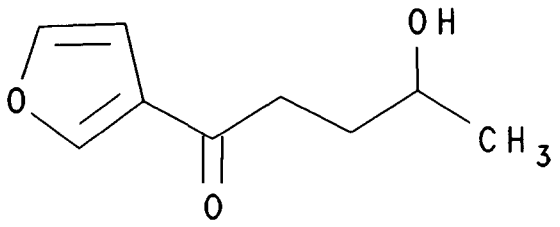
Diluted to a concentration of 0.5 mg/mL in 5% Dextrose Injection, USP, or 0.9% Sodium Chloride Injection, USP, iododeoxyuridine is also stable, exhibiting less than 4% decomposition in 14 days at room temperature (22-25 °C).

> **CAUTION**: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

IPOMEANOL

NSC - 349438



Chemical Name: 1-(3-Furanyl)-4-hydroxy-1-pentanone

CAS Registry Number: 55659-41-1

Molecular Formula: $C_9H_{12}O_3$ **M.W.:** 168.2

How Supplied: Injection, 20 mg, vial: supplied as a clear, colorless liquid containing 10 mg/mL of ipomeanol in 0.9% sodium chloride, USP, and sodium hydroxide to adjust pH to 4 to 7, in a 3 mL flint vial.

Injection, 500 mg, vial: supplied as a clear, colorless liquid containing 10 mg/mL of ipomeanol in 0.9% sodium chloride , USP, and sodium hydroxide to adjust pH to 4 to 7, in a 60 mL flint vial.

Storage: Store the intact vials stored under refrigeration (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. Three lots have maintained stability for 5 years under refrigeration (2-8 °C). The intact vials were unstable at elevated temperature (50 °C).

Aqueous solutions of ipomeanol are very stable over a pH range of 3 to 8.

Dilution of the ipomeanol to a concentration of 0.1 mg/mL in 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP, in glass bottles and PVC plastic bags yielded the following results:

Percentage of Initial Ipomeanol[a] Remaining in Solution

			Days		
Diluent	**Temp (°C)**	**Container**	**1**	**2**	**3**
D5W[b]	37	glass	100	100	100
		PVC	99	98	97
	25	glass	100	100	100
		PVC	99	99	98
	4	glass	100	100	100
		PVC	100	100	100
NS[c]	37	glass	99	99	100
		PVC	99	97	95
	25	glass	99	100	100
		PVC	98	98	98
	4	glass	100	100	100
		PVC	99	99	100

(a) Initial ipomeanol concentration 0.1 mg/mL
(b) 5% Dextrose Injection, USP
(c) 0.9% Sodium Chloride Injection, USP

CAUTION: Ipomeanol is a potent lung toxin (1,2,3). (Refer to toxicology information in the clinical brochure.) Great care should be taken by those preparing and handling ipomeanol to avoid contact with the product or its dilutions, including avoiding the formation of aerosols during preparation. The use of a suitable biological safety cabinet and protective gloves, gowns, masks, eye protection, etc., is strongly recommended.

Route of Administration: Intravenous

References:

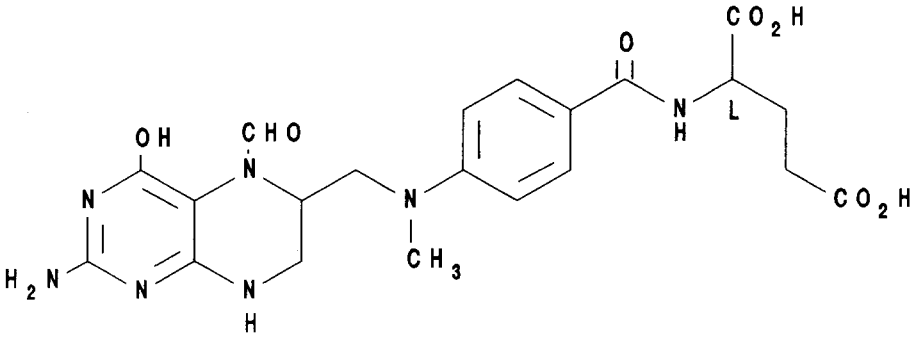
1. Wilson BJ, Yang DTC, and Boyd MR, Nature 227:521-522, 1970.

2. Boyd MR and Wilson BJ, J Agric Food Chem 20:428-430, 1972.

3. Elhawari M, et al: Proc AACR 28:440, 1987.

LEUCOVORIN CALCIUM

NSC - 3590



Chemical Name: N-[4-[[(2-Amino-5-formyl-1,4,5,6,7,8-hexahydro-4-oxo-6-pteridinyl)methyl]amino]benzoyl]-L-glutamic acid, calcium salt (1:1), (R,S)-

Other Names: Citrovorum Factor, Folinic Acid, Leucosar®, Wellcovorin®, Leucovorin Calcium (USAN)

CAS Registry Number: 1492-18-8

Molecular Formula: $C_{20}H_{25}N_7O_7 \cdot Ca$ **M.W.:** 511.5

How Supplied: For Injection, 50 mg (leucovorin equivalent present as calcium salt), vial, with sodium chloride, 45 mg. The product is prepared as a pale-yellow lyophilized powder in 10 mL flint vials.

For Injection, 500 mg (leucovorin equivalent present as calcium salt), vial, with sodium chloride, 80 mg. The product is prepared as a pale-yellow lyophilized powder in 30 mL flint vials.

Solution Preparation: 50 mg/vial: When constituted with 5 mL of Sterile Water for Injection, USP, each milliliter contains leucovorin calcium equivalent to leucovorin 10 mg and sodium chloride 9 mg. The pH of the solution is 6.0 to 8.0.

500 mg/vial : When constituted with 9.7 mL of Sterile Water for Injection, USP, each milliliter contains leucovorin calcium equivalent to leucovorin 50 mg and sodium chloride 8 mg. The pH of the solution is 6.5 to 8.5.

Storage: Store the intact vials at room temperature.

Stability: The intact vials are stable up to the expiration date when stored at room temperature (22-25 °C). Shelf-life studies on the 500 mg dosage form are ongoing.

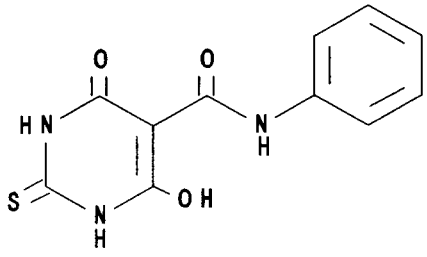
Constitution as directed results in a solution which is chemically stable for at least 7 days at room temperature.

> **CAUTION:** It is advised that the vials constituted with Sterile Water for Injection, USP, be discarded within 8 hours of initial entry.

Route of Administration: Intramuscular, intravenous, oral

MERBARONE

NSC - 336628



Chemical Name: Hexahydro-4,6-dioxo-N-phenyl-2-thioxo-5-pyrimidinecarboxamide

Other Name: 5-Carboxyanilino-2-thiobarbituric acid

CAS Registry Number: 97534-21-9

Molecular Formula: $C_{11}H_9N_3O_3S$ **M.W.**: 263.3

How Supplied: For injection, 200 mg, vial: supplied as a lyophilized powder with 400 mg meglumine in 30 mL amber vials.

Solution Preparation: 200 mg/vial: When constituted with 19.5 mL of Sterile Water for Injection, USP, each milliliter contains 10 mg of merbarone with 20 mg of meglumine at pH 9 to 10.

The solution may be light yellow, peach-colored, or light pink in color.

Storage: Refrigerate the intact vials (2-8 °C) and protect from light.

Stability: Shelf-life surveillance of the intact vials is ongoing. The intact vials are stable for 5 years at room temperature (22-25 °C). The intact vials are stable for at least one year at elevated temperature (50 °C).

Constitution as directed results in a solution which is stable for 15 days at room temperature.

Further dilution to a concentration of 0.1 mg/mL with 5% Dextrose Injection, USP, in glass or PVC plastic containers also results in a solution exhibiting little or no decomposition after two weeks of storage at 0 °C, room temperature, and 37 °C.

Merbarone is incompatible with metal ions such as Na^+,K^+,Ca^{++}, and Mg^{++}. A precipitate may form if the drug is diluted in solutions containing these ions. Dilution of merbarone with isotonic sodium chloride solution has resulted in the formation of crystals in 30 minutes. Therefore, merbarone should not be diluted with solutions which contain metal ions.

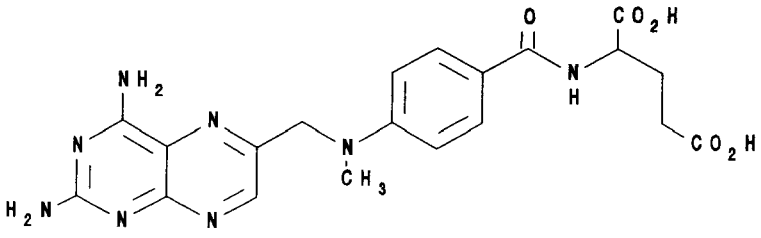
CAUTION: This single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

METHOTREXATE

NSC - 740

The following information applies to the investigational dosage forms of methotrexate. For information regarding the commercially available dosage form, consult the package inserts provided by the commercial suppliers.



Chemical Name: N-[4-[[(2,4-diamino-6-pteridinyl)-methyl]methylamino]benzoyl]glutamic acid, L-

Other Names: MTX, Amethopterin, 4-amino-10-methyl-folic acid, Mexate®, Folex®, Rheumatrex®, Methotrexate (USAN)

CAS Registry Number: 59-05-2

Molecular Formula: $C_{20}H_{22}N_8O_5$ **M.W.:** 454.5

How Supplied: For injection, 1.0 gm, vial: supplied as a yellow lyophilized powder of the sodium salt of methotrexate in 30 mL amber vials.

Solution Preparation: When constituted with 19.4 mL of Sterile Water for Injection, USP, each milliliter contains 50 mg of methotrexate as the sodium salt. The pH of the constituted solution is 7.8-8.8.

The 1.0 gm/vial may also be constituted with 0.9% Sodium Chloride Injection, USP, 5% Dextrose Injection, USP, or 5% Dextrose in 0.9% Sodium Chloride Injection, USP.

Storage: Store the intact vials at room temperature.

Stability: Shelf-life surveillance of the intact vials is ongoing. Intact vials are stable for 5 years at room temperature (22-25 °C). Intact vials are stable for at least one year at elevated temperature (50 °C).

Constitution of the vials as recommended results in a clear, yellow solution which is chemically stable for at least 7 days at room temperature (22-25 °C).

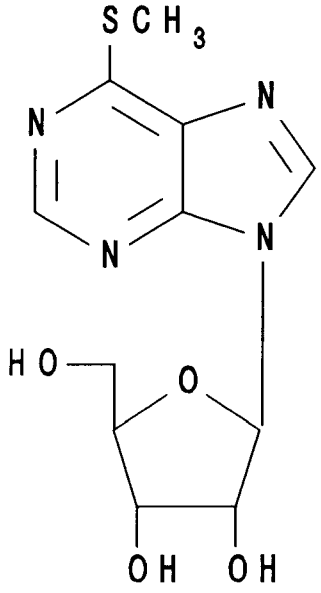
Further dilution of the constituted solutions with up to 500 mL of 5% Dextrose Injection, USP, 0.9% Sodium Chloride Injection, USP, or 5% Dextrose in 0.9% Sodium Chloride Injection, USP, does not alter solution stability.

CAUTION: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

6-METHYLMERCAPTOPURINE RIBOSIDE

NSC - 40774



Chemical Name: 6-Methylthio-9-β-D-ribofuranosyl-9H-purine

Other Names: 6-MMPR; 6-Methyl MP-riboside

CAS Registry Number: 342-69-8

Molecular Formula: $C_{11}H_{14}N_4O_4S$ **M.W.:** 298.3

How Supplied: Sterile, 50 mg, vial: supplied as a white lyophilized powder with 100 mg of mannitol, USP, in a 20 mL flint vial.

Solution Preparation: 50 mg/vial: When constituted with 10 mL of 0.9% Sodium Chloride Injection, USP, each milliliter of the resultant solution contains 5 mg of 6-methylmercaptopurine riboside and 10 mg of mannitol, USP, at pH 6.0 to 7.5.

CAUTION: Use only if a vacuum is present.

Storage: Store the intact vials under refrigeration (2-8 °C).

Stability: Intact vials are stable for at least four years when stored at room temperature (22-25 °C). Intact vials are stable for at least one year when stored at elevated temperature (50 °C).

Constituted solutions of 6-methylmercaptopurine riboside exhibit no decomposition for at least 24 hours at room temperature.

Note: A precipitate may be present after constitution. However, the precipitate is 6-MMPR and can be easily redissolved by warming under hot tap water.

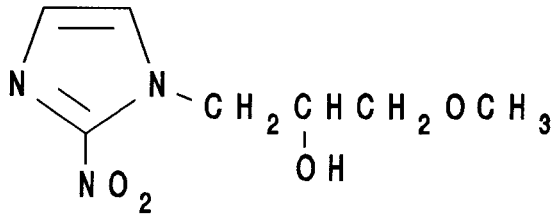
Further dilution to a concentration of 0.1 mg/mL in 5% Dextrose in 0.9% Sodium Chloride Injection, USP, also results in solutions exhibiting no decomposition for at least 24 hours at room temperature.

CAUTION: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

MISONIDAZOLE

NSC - 261037



Chemical Name: α-(Methoxymethyl)-2-nitro-1H-imidazole-1-ethanol

Other Names: Ro-7-0582, 1-(2-nitroimidazolyl)-3-methoxy-2-propanol

CAS Registry Number: 13551-87-6

Molecular Formula: $C_7H_{11}N_3O_4$ **M.W.:** 201.2

How Supplied: For injection, 500 mg, vial: supplied as a light yellow lyophilized powder with 300 mg of mannitol, USP, in 30 mL amber vials.

Solution Preparation: 500 mg/vial: When constituted with 19.6 mL of 0.9% Sodium Chloride Injection, USP, or Sterile Water for Injection, USP, each milliliter contains 25 mg of misonidazole and 15 mg of mannitol, USP, pH 5.0 to 7.0.

> **CAUTION:** Some vials contain undissolved misonidazole after constitution. Complete reconstitution can be achieved by warming the mixture at 40 °C or constituting with 25 mL of diluent initially for a misonidazole concentration of 20 mg/mL.

Storage: Store the vials at room temperature (22-25 °C).

Stability: Shelf-life surveillance studies are continuing. The intact vials are stable for at least 3 years at room temperature (22-25 °C). The intact vials are stable for at least one year when stored at elevated temperature (50 °C).

Constitution of the vials as directed results in a solution which is chemically stable for at least 14 days at room temperature, exhibiting less than 2% decomposition.

Further dilution of the freshly constituted solution to a concentration of 1 gm/L in 5% Dextrose Injection, USP, resulted in less than 1% decomposition in 14 days at room temperature.

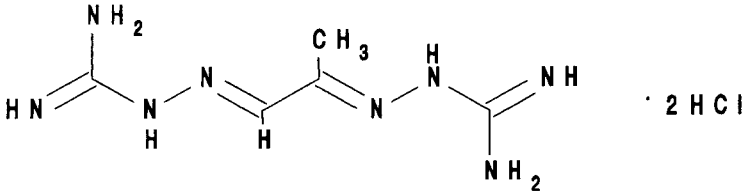
The stability of solutions of misonidazole is unaffected by exposure to light.

> **CAUTION:** The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

MITOGUAZONE

NSC - 32946



Chemical Name: 2,2'-(1-methyl-1,2-ethanediylidene)-bis(hydrazinecarboximidamide), dihydrochloride

Other Names: Methyl GAG, Methylglyoxal Bisguanylhydrazone Dihydrochloride, MGBG, Methyl-G

CAS Registry Number: 7059-23-6

Molecular Formula: $C_5H_{12}N_8 \cdot 2HCl$ **M.W.:** 257.2

How Supplied: Sterile, 1.0 gm, vial: each 30 mL flint vial contains 1.0 gm of mitoguazone dihydrochloride in lyophilized form.

Solution Preparation: 1.0 gm/vial: When constituted with 9.3 mL of 0.9% Sodium Chloride Injection, USP, each milliliter contains 100 mg of mitoguazone dihydrochloride at pH 3.0 to 5.0.

Storage: Store the intact vials at room temperature.

Stability: When stored at room temperature, intact vials of mitoguazone dihydrochloride are stable for at least 4 years.

Constitution with 0.9% Sodium Chloride Injection, USP, as directed results in a solution which shows no decomposition in 48 hours either under refrigeration (2-8 °C) or at room temperature (22-25 °C).

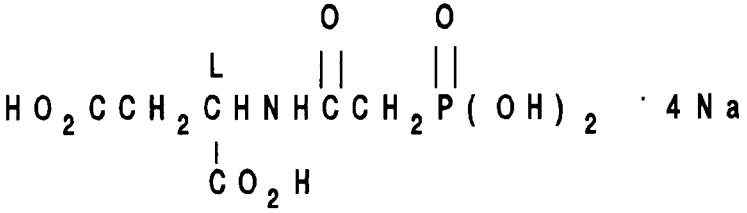
Further dilution to a concentration of 2 mg/mL in 5% Dextrose in 0.9% Sodium Chloride Injection, USP, also results in a physically and chemically stable solution. No detectable decomposition occurs in 7 days either under refrigeration or at room temperature. The presence of ambient light does not affect the stability of mitoguazone dihydrochloride.

> **CAUTION**: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

PALA

NSC - 224131



Chemical Name: N-(Phosphonoacetyl)sparfosic acid, L-

Other Names: Sparfosate Sodium (USAN), N-Phosphonoacetyl-L-Aspartate Disodium

CAS Registry Number: 51321-79-0

Molecular Formula: $C_6H_8NO_8P$ **M.W.:** 299.1

How Supplied: Injection, 1 gm, flint ampule: supplied as 10 mL of solution containing 100 mg/mL of PALA disodium, with 1 mg/mL edetate disodium and sodium hydroxide to adjust to pH 6.5 to 7.5 in Water for Injection, USP.

Injection, 500 mg, vial: supplied as 5 mL of solution containing 100 mg/mL of PALA disodium, with 1 mg/mL edetate disodium and sodium hydroxide to adjust to pH 6.5 to 7.5 in Water for Injection, USP, in a 10 mL flint vial.

Storage: Store the intact ampules and vials at room temperature.

Stability: Shelf-life surveillance of the intact vials is ongoing. Three lots of vials are stable for 2 years at room temperature (22-25 °C).

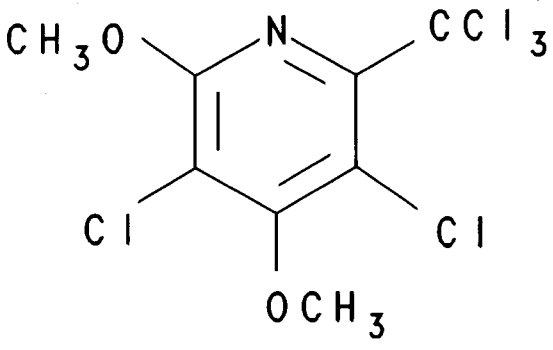
Intact ampules are stable for 5 years at room temperature (22-25 °C) and for at least one year at elevated temperature (50°C). A fine precipitate has been observed in two lots of ampules after storage for 4 years at refrigeration and room temperature.

Dilution of PALA disodium to a concentration of 1 mg/mL in 5% Dextrose Injection, USP, or 0.9% Sodium Chloride Injection, USP, results in a solution which is chemically stable for at least 2 weeks at room temperature (22-25 °C).

Route of Administration: Intravenous

PENCLOMEDINE

NSC - 338720



Chemical Name: Pyridine,3,5-dichloro-2,4-dimethyloxy-6-(trichloromethyl)-

CAS Registry Number: 108030-77-9

Molecular Formula: $C_8H_6Cl_5NO_2$ **M.W.:** 325.4

How Supplied: Sterile, 100 mg, vial: supplied as a 10 mg/mL emulsion in 10 mL flint vials. Each milliliter also contains 30 mg of egg lecithin, 20 mg of glycerin, USP, and 100 mg of soybean oil, in water for injection, USP. The pH is adjusted to approximately 8 with sodium hydroxide or hydrochloric acid. The particle size range for the emulsion is from 0.2 microns to 0.5 microns.

Storage: Store the intact vials under refrigeration (2-8 °C).

Stability and Compatibility:

Shelf-life surveillance of the intact vials is ongoing.

Penclomedine emulsions may be diluted up to 1:10 with the following i.v. fluids:

water for injection, USP;
0.9% sodium chloride injection, USP;
5% Dextrose Injection, USP;
10% Intralipid®.

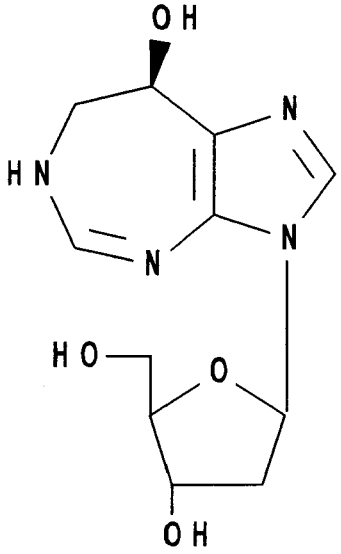
No physical or chemical changes were observed when the above admixtures were stored at room temperature for 8 hours either in glass bottles or plastic I.V. bags.

Route of Administration: Intravenous

Note: The use of in-line filters is not recommended.

PENTOSTATIN

NSC - 218321



Chemical Name: 3-(2-Deoxy-β-D-erythro-pentofuranosyl)-3, 6,7,8-tetrahydroimidazo[4,5-d][1,3]diazepin-8-ol, (R)-

Other Names: 2'-Deoxycoformycin, Co-Vidarabine, Nipent, Pentostatin (USAN)

CAS Registry Number: 53910-25-1

Molecular Formula: $C_{11}H_{16}N_4O_4$ **M.W.:** 268.3

How Supplied: For injection, 10 mg, vial: supplied as a lyophilized powder with 50 mg mannitol, USP, and sodium hydroxide to adjust the pH in 5 mL flint vials.

Solution Preparation: 10 mg/vial: When constituted with 5 mL of 0.9% Sodium Chloride Injection, USP, each milliliter contains 2 mg of pentostatin and 10 mg of mannitol, USP, at pH 6.7 to 8.7.

Storage: Refrigerate the intact vials (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. Intact vials are stable for 5 years under refrigeration but have gone below 90% of labeled amount by 3 years storage at room temperature (22-25 °C). Intact vials are unstable when stored at elevated temperature (50 °C) for one year. The intact vials bear a "do not use after" date.

Constitution with 0.9% Sodium Chloride Injection, USP, results in a solution which is chemically stable at room temperature (22-25 °C) for at least 72 hours, exhibiting about 2 to 4% decomposition.

When diluted to a concentration of 10 mg per 500 mL in 0.9% Sodium Chloride Injection, USP, or Lactated Ringer's Injection, USP, pentostatin is chemically stable for at least 48 hours at room temperature (22-25 °C), exhibiting approximately 0 to 4% decomposition.

At a concentration of 10 mg per 500 mL in 5% Dextrose Injection, USP, approximately 2% decomposition occurs in 24 hours at room temperature. As much as 8 to 10% loss has been reported to occur in 48 hours.

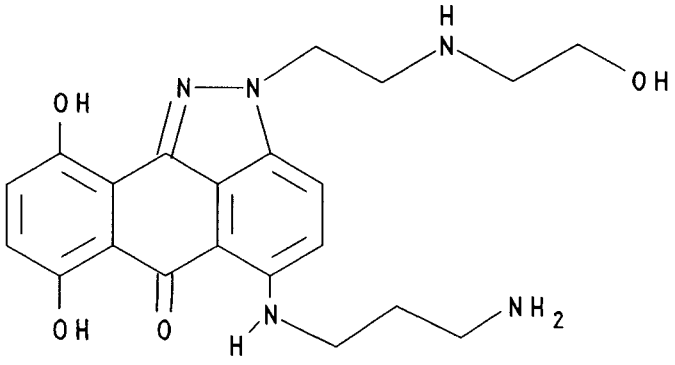
No potency loss was detected in the constituted solution or in admixtures in 5% Dextrose Injection, USP, or 0.9% Sodium Chloride Injection, USP, when refrigerated at 5 °C over 96 hours.

> **CAUTION**: This single-use product contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

PIROXANTRONE

NSC - 349174



Chemical Name: 5-[(3-Aminopropyl)amino]-7,10-dihydroxy-2-[2-[(2-hydroxyethyl)amino]ethyl]-anthra[1,9-cd]-pyrazol-6(2H)-one, dihydrochloride

Other Names: Oxantrazole Hydrochloride; Anthrapyrazole Dihydrochloride, Piroxantrone Hydrochloride (USAN)

CAS Registry Number: 105118-12-5

Molecular Formula: $C_{21}H_{25}N_5O_4 \cdot 2HCl$ **M.W.:** 484.4

How Supplied: For Injection, 50 mg, vial: supplied as a deep red lyophilized powder with 50 mg of mannitol, USP, in a 10 mL flint vial.

Solution Preparation: 50 mg/vial: When constituted with 2.5 mL of Sterile Water for Injection, USP, each milliliter contains 20 mg of piroxantrone HCl and 20 mg of mannitol, USP, at pH 4 to 6.

Storage: Store the intact vials in the freezer (-10 to -20 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. One lot has maintained stability for at least 36 months at room temperature (22-25 °C). The intact vials were unstable at elevated temperature (50 °C).

Solutions of piroxantrone HCl are most stable below pH 6. A study of piroxantrone HCl at pH values from 3.4 to 8.0 in various buffer systems at 70 °C yielded the following half-life results:

pH	Approx. $t_{1/2}$ (70 °C)
8.0	5 min.
7.3	18 min.
6.4	2 hr.
5.6	7 hr.
4.5	32 hr.
3.4	41 hr.

Constitution as recommended results in a solution which is chemically stable for 14 days under refrigeration, at room temperature, and at 37 °C.

Further dilution to a concentration of 0.1 mg/mL in 0.9% Sodium Chloride Injection, USP, and 5% Dextrose Injection, USP, in glass bottles and plastic bags yielded the following results:

Percentage Piroxantrone HCl[a]
Remaining In Infusion Solutions

Diluent	Temp. (°C)	Days 1	2	3	4
NS[b]	37	98	95	93	85
	25	99	99	98	90
	4	100	100	100	100
D5W[c]	37	100	100	100	96
	25	100	100	100	96
	4	100	100	100	100

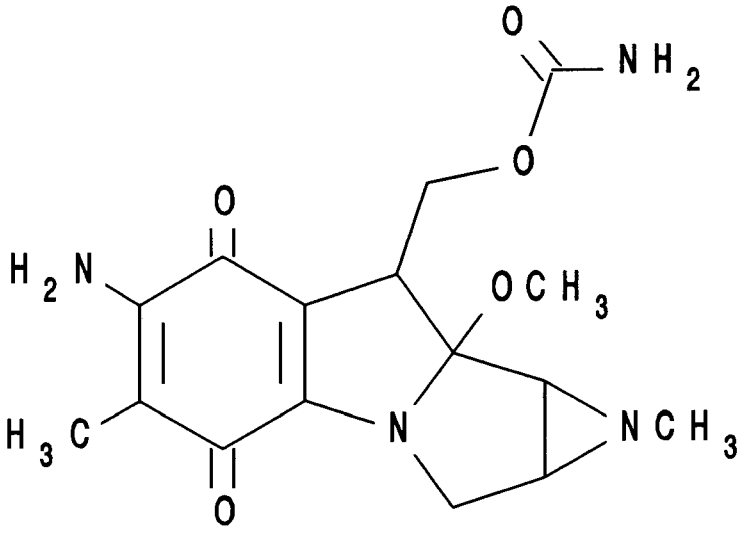
(a) Initial concentration 0.1 mg/mL
(b) 0.9% Sodium Chloride Injection, USP
(c) 5% Dextrose Injection, USP

CAUTION: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

PORFIROMYCIN

NSC - 56410



Chemical Name: Carbamic Acid, ester with 6-amino-1,1a,2,8,8a,8b-hexahydro-8-(hydroxymethyl)-8a-methoxy-1,5 dimethylazirino[2',3':3,4]pyrrolo-[1,2α]indole-4,7-dione

Other Names: N-Methyl-mitomycin C; U-14743, Regamycin, Porfiromycin (USAN)

CAS Registry Number: 801-52-5

Molecular Formula: $C_{16}H_{20}N_4O_5$ **M.W.:** 348.4

How Supplied: For injection, 15 mg, vial: supplied as a lyophilized powder with 100 mg of mannitol, USP, 24.2 mg of tris(hydroxymethyl)aminomethane, and hydrochloric acid for pH adjustment in a 10 mL flint vial.

Solution Preparation: 15 mg/vial: When constituted with 9.9 mL of Sterile Water for Injection, USP, each milliliter of the deep violet solution contains 1.5 mg of porfiromycin, and the pH of the solution is buffered to 7.8 to 8.1.

Storage: Refrigerate the intact vials (2-8 °C).

Stability: Shelf-life surveillance on the intact vials is ongoing.

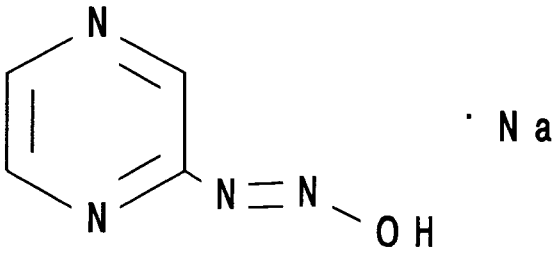
Constitution as recommended results in a solution which is stable for at least eight hours at temperature (22-25 °C).

> **CAUTION**: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

PYRAZINE DIAZOHYDROXIDE

NSC - 361456



Chemical Name: N-Nitrosopyrazinamine, sodium salt

Other Names: Sodium N-Nitroso-Pyrazinamine, PZDH

CAS Registry Number: 103829-56-7

Molecular Formula: $C_4H_3N_4O \cdot Na$ **M.W.:** 146.1

How Supplied: Sterile, 500 mg, vial: supplied as a yellow lyophilized powder in 20 mL amber vials. The pH has been adjusted with hydrochloric acid.

Solution Preparation: 500 mg/vial: When constituted with 9.8 mL of Sterile Water for Injection, USP, each milliliter contains 50 mg of pyrazine diazohydroxide at a pH of 9.0 to 10.5.

Storage: Store the intact vials in the freezer (-10 to -20 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing.

The constituted solution is chemically and physically stable for 24 hours at room temperature.

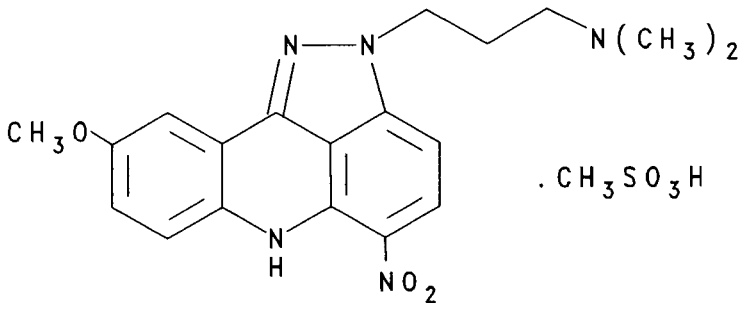
When the constituted solution is diluted in 0.9% Sodium Chloride, USP, or 5% Dextrose in Water, USP, to a concentration of 1 mg/mL in glass bottles the solution is stable for 24 hours at refrigerated temperature (4 °C) and 4 hours at room temperature. The stability in PVC plastic bags was reduced to 8 hours at refrigerated temperatures (4 °C) and 4 hours at room temperature.

> **CAUTION:** The single-use freeze dried dosage form contains no antibacterial preservatives. Therefore, the constituted solution should be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

PYRAZOLOACRIDINE

NSC - 366140



Chemical Name: 9-Methoxy-N,N-dimethyl-5-nitropyrazolo-[3,4,5-kl] acridine-2(6H)-propanamine, monomethanesulfonate

CAS Registry Number: 99009-20-8

Molecular Formula: $C_{19}H_{21}N_5O_3 \cdot CH_4O_3S$ **M.W.:** 463.5

How Supplied: Sterile, 100 mg, vial: supplied as a orange-red lyophilized powder with sodium hydroxide added for pH adjustment in 10 mL flint vials.

Solution Preparation: 100 mg/vial: constitution with 5.0 mL of Sterile Water for Injection, USP results in a clear, orange-red solution at a pH of 4.5 to 6.0 containing 20 mg/mL of pyrazoloacridine base.

Further dilution to 0.1 mg/mL with Dextrose 5% in Water, USP and Sodium Chloride 0.9%, USP in both glass bottles and plastic bags resulted in solutions that were stable for eight days at storage temperatures of 4, 25, and 37 °C. Solutions are chemically and physically stable for 14 days at 4 °and 25 °C.

Storage: Store at room temperature.

Stability: Stability studies of the intact vials are ongoing. One lot has maintained stability for at least 18 months at room temperature (22-25 °C). The intact vials were stable at elevated temperature (50 °C) for 12 months.

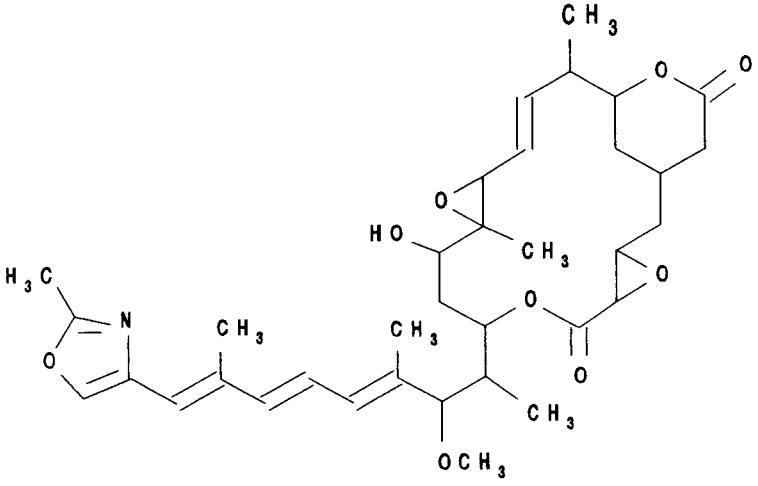
The constituted solution is stable for at least 24 hours at room temperature.

> **CAUTION:** This single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

RHIZOXIN
WITH DILUENT

NSC - 332598



Chemical Name: 10-Hydroxy-8-(2-methoxy-1,3,7-trimethyl-8-(2-methyl-4-oxazolyl)-3,5,7-octatrienyl)-11,16-dimethyl-4,7,12,18-tetraoxatetracyclo(15.3.1.03,5.011,13)heneicos-14-ene-6,19-dione,*(1S−(1R*,3R*,5S*,8R*(1R*,2S*,3E,5E,7E),10R*,11S*,13S*,14E,16S*,17S*))*-

Other Name: WF 1360

CAS Registry Number: 90996-54-6

Molecular Formula: $C_{35}H_{47}NO_9$ **M.W.:** 625.8

How Supplied:

NSC - 332598 Sterile, 5 mg, vial: supplied as a white lyophilized powder, with 25 mg of mannitol, USP, and 25 mg of ascorbic acid, USP, in 5 mL flint vials. The pH is adjusted with NaOH to 5.6.

NSC - 649688 Sterile diluent containing propylene glycol 80% and ethanol 20% (v/v), 2.5 mL.

Solution Preparation:
(1.) Constitute the vial of rhizoxin with 2.5 mL of the special diluent first.

(2.) Add 2.5 mL of sterile water for injection. The resulting solution will contain rhizoxin 1 mg/mL in 40% propylene glycol(v/v), 10% ethanol,(v/v), in sterile water for injection.

(3.) For I.V. infusion, further dilute in 10% Fat Emulsion (1:100 up to 1:10 v/v). Rhizoxin will precipitate in Saline and Dextrose solutions.

Storage: Refrigerate the intact vials (2-8 °C)

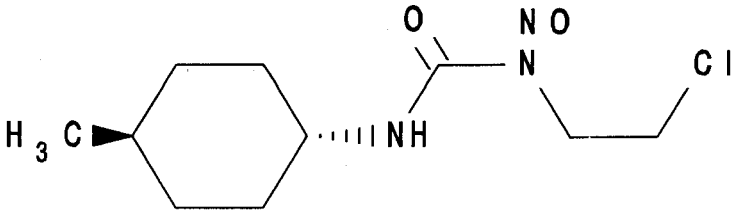
Stability: Shelf-life studies are ongoing.

CAUTION: Contains no antibacterial preservatives.
Use within eight hours.

Route of Administration: Intravenous

SEMUSTINE

NSC - 95441



Chemical Name: N-(2-Chloroethyl)-N'-(4-methylcyclohexyl)-N-nitrosourea, trans-

Other Names: Methyl CCNU, MeCCNU, Semustine (USAN)

CAS Registry Number: 13909-09-6

Molecular Formula: $C_{10}H_{18}ClN_3O_2$ **M.W.:** 247.7

How Supplied: Capsules, 10 mg: Each opaque, white, hard gelatin capsule also contains the inert ingredients mannitol, USP, magnesium stearate, and colloidal silicon dioxide.

Capsules, 50 mg: Each opaque, brown, hard gelatin capsule also contains the inert ingredients mannitol, USP, magnesium stearate and colloidal silicon dioxide.

Capsules, 100 mg: Each opaque, brown and black, hard gelatin capsule also contains the inert ingredients mannitol, USP, magnesium stearate and colloidal silicon dioxide.

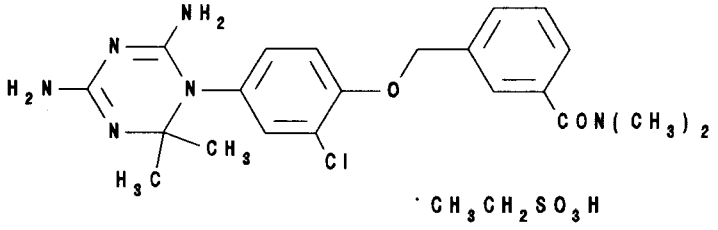
Storage: Refrigerate the capsules in tightly sealed bottles (2-8 °C). A desiccant packet is enclosed in each bottle.

Stability: Shelf-life surveillance of the intact capsules is ongoing. The capsules stored in intact bottles are stable for at least 4 years at refrigeration temperature (2-8 °C) and for at least 1 year at room temperature (22-25 °C). Storage of the capsules at 40 °C for 7 days resulted in little or no decomposition. However, 3 months of storage at over 40 °C resulted in 20-30% degradation.

Route of Administration: Oral

SOLUBLE BAKER'S ANTIFOL

NSC - 139105



Chemical Name: Ethanesulfonic acid, compound with α-[2-chloro-4-(4,6-diamino-2,2-dimethyl-s-triazin-1(2H)-yl))phenoxy]-N,N-dimethyl-m-toluamide (1:1)

Other Names: Ethanesulfonic Acid Compound, BAF, Triazinate, TZT

CAS Registry Number: 41191-04-2

Molecular Formula: $C_{29}H_{25}ClN_6O_2 \cdot C_2H_6O_3S$ **M.W.:** 539.0

How Supplied: Sterile, 100 mg, vial: supplied as a white lyophilized powder in 10 mL flint vials.

Solution Preparation: 100 mg/vial: When constituted with 5 mL of Sterile Water for Injection, USP, each milliliter contains 20 mg of Soluble Baker's Antifol with a pH of 5.0 to 8.0.

Storage: Store the intact vials at room temperature.

Stability: Shelf-life surveillance of the intact vials is ongoing. Intact vials are stable for at least 4 years at room temperature (22-25 °C). Intact vials are stable for at least one year when stored at elevated temperature (50 °C).

Constitution as recommended results in a solution which is chemically stable for at least 4 days at room temperature. Exposure to room light does not affect the stability of the constituted solution.

Further dilution to a concentration of 250 mg/500 mL in 5% Dextrose in 0.9% Sodium Chloride Injection, USP, did not alter the stability in solution.

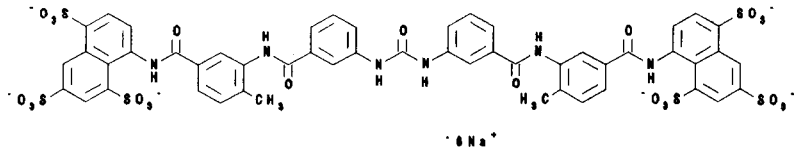
> **CAUTION:** The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

SURAMIN SODIUM

NSC - 34936

The product described below is supplied by Miles, Inc., New Haven, Connecticut, for clinical trials sponsored by the Division of Cancer Treatment, National Cancer Institute.



Chemical Name: 8,8'-[Carbonylbis[imino-3,1-phenylene-carbonylimino(4-methyl-3,1-phenylene)carbonylimino]]bis-1,3,5-naphthalenetrisulfonic acid, hexasodium salt

Other Names: Moranyl; Bayer 205; Germanin; Fourneau 309 Antrypol; Naganol; Naganin; Naphuride Sodium, Suramin Sodium (USAN)

CAS Registry Number: 129-46-4

Molecular Formula: $C_{51}H_{34}N_6O_{23}S_6 \cdot 6Na$ **M.W.:** 1429.2

How Supplied: Sterile, 1 gm, vial: supplied as a white powder in 10 mL flint vials.

Solution Preparation: 1 gm/vial: When constituted with 10 mL of Sterile Water for Injection, USP, to yield a 10% (100 mg/mL) solution of suramin sodium.

Storage: Store the intact vials at room temperature.

Stability: The intact vials are stated by the manufacturer to be stable for five years at room temperature.

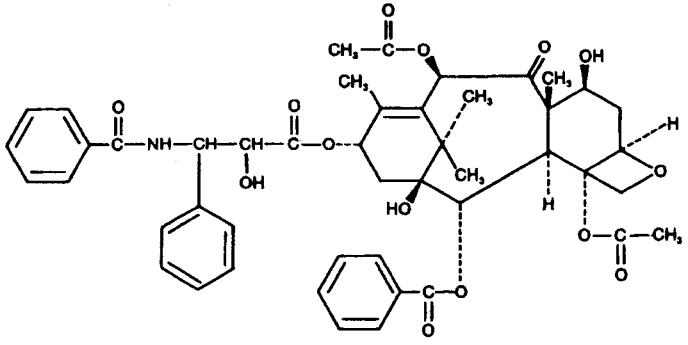
Dilution of suramin sodium to concentrations of 2, 10, and 20 mg/mL in 0.9% Sodium Chloride Injection, USP, and Sterile Water for Injection, USP in PVC containers results in solutions which are physically stable and exhibit no decomposition over 21 days at room temperature.

Dilutions of suramin sodium to a concentration of 8 mg/mL in 5% Dextrose in Water, USP in Deltec® cassette reservoirs were stable for three weeks at 4 °C and -20 °C. However, special care must be taken to avoid precipitation at 4 °C and -20 °C. Inspect all solutions for precipitation before use.

Route of Administration: Intravenous

TAXOL

NSC - 125973



Chemical Name: β-(Benzoylamino)-α-hydroxy-benzenepropanoic acid, 6,12b-bis(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-4,11-dihydroxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, [2aR-[2aα,4β,4aβ,6β,9α(αR*,βS*),11α,12α,12aα,12bα]]-

Other Names: Taxol®, Paclitaxel

CAS Registry Number: 33069-62-4

Molecular Formula: $C_{47}H_{51}NO_{14}$ **M.W.**: 853.9

Description: Taxol is a poorly soluble plant product isolated from *Taxus brevifolia.*

How Supplied: Injection, 30 mg, ampule/vial: 6 mg/mL, 5 mL, in polyethoxylated castor oil (Cremophor EL®) 50%, and dehydrated alcohol, USP, in 5 mL flint ampules/vials.

Solution Preparation: Taxol concentrations from 0.3 mg/mL to 1.2 mg/mL may be obtained by diluting the solution with either 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP.

> **CAUTION**: PVC bags and sets should be avoided due to appreciable leaching of DEHP(1,2,3). This solution must be diluted before use and given by slow intravenous infusion.

NOTE: A small number of fibers (within acceptable levels of the USP Particulate Matter Test for LVPs) have been observed after dilution. Therefore, inline filtration is necessary with all taxol infusions. Solutions exhibiting excessive particulate formation should not be used. Analyses of solutions filtered through IVEX-2® and IVEX-HP®(Abbott) 0.2 μm filters showed no appreciable loss of potency.

Storage: Refrigerate the intact ampules and vials (2-8 °C).

Stability: Shelf-life surveillance of the ampules and vials is ongoing. Three lots have maintained stability for at least 18 months at room temperature (22-25 °C). The intact vials were unstable at elevated temperature (50 °C).

Solutions of taxol diluted to the above concentrations are both chemically and physically stable for at least 27 hours at room temperature. All solutions exhibit a slight haze which is common to all products containing nonionic surfactants.

Route of Administration: Intravenous (slow infusion over one hour or more)

References:

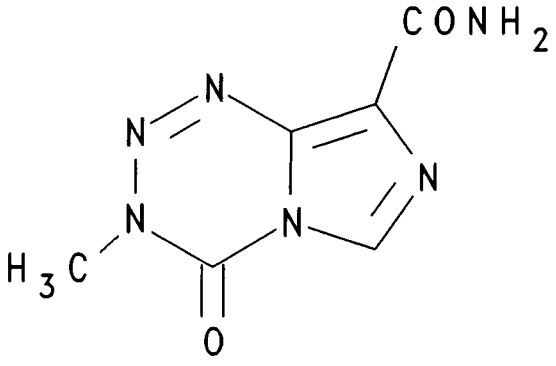
1. Waugh, W.N., Trissel, L.A., Stella, V.J. Stability, Compatabilty, and Plasticizer Extraction of Taxol (NSC-125973) Injected Diluted in Infusion Solutions and Stored in Various Containers. Am J Hosp Pharm 48:1520-1524, 1991.

2. Harris, G.W. Di(2-ethylhexyl) phthalate (DEHP) in Medical Products. Proceedings of the Conference on Phthalates, National Toxicology Program/Interagency Regulatory Liaison Group, June 9, 1981. pp 179-195

3. Jaeger, R.J., Rubin, R.J. Migration of a Phthalate Ester Plasticizer from Polyvinyl Chloride Blood Bags into Stored Human Blood and Its Localization in Human Tissues. N.Engl J Med 287:1114-1118, 1972.

TEMOZOLOMIDE

NSC - 362856



Chemical Name: 3,4-Dihydro-3-methyl-4-oxoimidazo[5,1-*d*]-1,2,3,5-tetrazine-8-carboxamide.

Other Name: Temozolomide (USAN)

CAS Registry Number: 85622-93-1

Molecular Formula: $C_6H_6N_6O_2$ **M.W.:** 194.1

How Supplied: Capsules, 100 mg: Each brown/black #1 capsule also contains the inert ingredients anhydrous lactose, corn starch, primogel, magnesium stearate, and cab-o-sil. There are 100 capsules per bottle.

Capsules, 20 mg: Each white/white #1 capsule also contains the inert ingredients anhydrous lactose, corn starch, primogel, magnesium stearate, and cab-o-sil. There are 100 capsules per bottle.

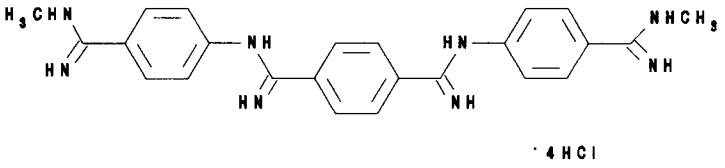
Storage: Store the capsules at refrigerated temperature (4-8°C).

Stability: Shelf-life studies are ongoing.

Route of Administration: Oral

TEREPHTHALAMIDINE

NSC - 57155



Chemical Name: N,N''-Bis[p−(methylamidino)phenyl]-terephthalamidine, tetrahydrochloride

Other Names: Symetamine

CAS Registry Number: 2053-23-8

Molecular Formula: $C_{24}H_{26}N_8 \cdot 4HCl$ **M.W.:** 572.4

How Supplied: For injection, 250 mg, vial: supplied as a lyophilized powder with 250 mg of terephthalamidine as the free base at a pH of 3 to 5 in a 20 mL flint vial.

Solution Preparation: 250 mg/vial: When constituted with 10 mL of Sterile Water for Injection, USP, each mL will contain terephthalamidine HCl equivalent to 25 mg of terephthalamidine free base. Complete reconstitution may require warming under a hot water tap to at least 37 °C.

Storage: Intact vials may be stored at room temperature.

Stability: Shelf-life studies are ongoing.

Constitution as directed results in a 25 mg/mL solution which is chemically stable for eight days at room temperature.

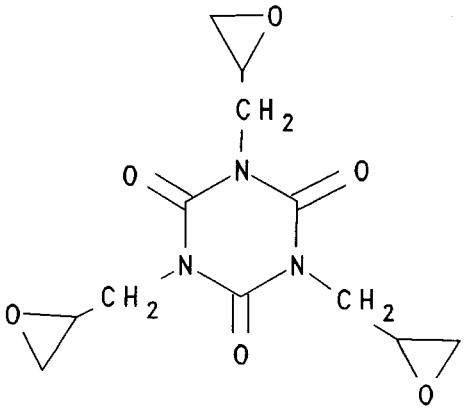
Further dilution of the constituted solution to a concentration of 0.2mg/mL in 5% Dextrose Injection, USP, or 0.9% Sodium Chloride Injection, USP, in PVC plastic bags and in glass bottles yielded a solution which was chemically stable for six days at room temperature.

> **Caution:** The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within eight hours after initial entry.

Route of Administration: Intravenous

TEROXIRONE

NSC - 296934



Chemical Name: 1,3,5-Tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione

Other Names: Henkel's Compound; Triazinetrione triepoxide; α-Triglycodyl isocyanurate; α-TGI, Teroxirone (USAN)

CAS Registry Number: 2451-62-9

Molecular Formula: $C_{12}H_{15}N_3O_6$ **M.W.**: 297.3

How Supplied: For injection, 100 mg, vial: supplied as a white lyophilized powder with 200 mg of mannitol, USP, in a 20 mL flint vial.

Solution Preparation: 100 mg/vial: When constituted with 10 mL of Sterile Water for Injection, USP, each milliliter contains 10 mg of teroxirone and 20 mg of mannitol, USP, at pH 6.0 to 8.0.

Storage: Store the intact vials under refrigeration.

Stability: Shelf-life surveillance of the intact vials is ongoing. Intact vials are stable for at least 3 years at refrigeration temperature (2-8 °C). Intact vials are unstable when stored at elevated temperature (50 °C).

Solutions of teroxirone are most stable at around pH 6. A study of teroxirone 5 mg/mL in various buffer systems over a pH range of 3 to 9.7 at 25 °C yielded the following data at 4 and 24 hours:

Percent Of Teroxirone Remaining

pH	4 Hrs.	24 Hrs.
3	89	49
5.5	97	76
6.4	97	79
7.5	91	57
9.7	92	49

The constituted solution of teroxirone exhibits approximately 2 to 5% decomposition in 4 hours at room temperature (22-25 °C).

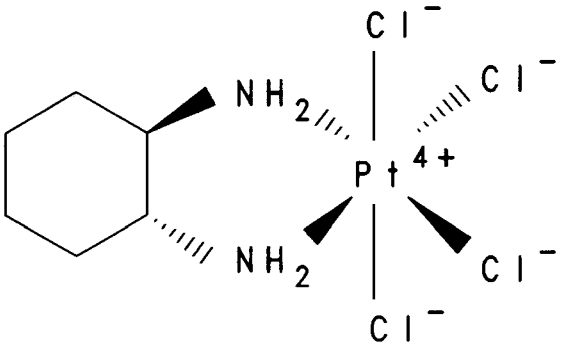
Further dilution to a concentration of 0.1 mg/mL in 0.9% Sodium Chloride Injection, USP, results in a solution exhibiting about 2% decomposition in 2 hours and 8 to 10% in 4 hours at room temperature (22-25 °C) or under refrigeration (2-8 °C). Teroxirone is much less stable in 5% Dextrose Injection, USP, exhibiting approximately 12% decomposition in 2 hours and 17% in 4 hours.

At concentrations of 0.19, 1.0 and 2.4 mg/mL in 0.9% Sodium Chloride Injection, USP, at 37 °C, teroxirone decomposes 10% in 111, 126, and 162 minutes, respectively. After 4 hours at 37 °C, teroxirone losses of 21, 16, and 15% were observed at the three concentrations, respectively.

Route of Administration: Intravenous

TETRAPLATIN

NSC - 363812



Chemical Name: Platinum, tetrachloro(1,2-cyclohexanediamine-N,N')-, (OC-6-22-(trans))-

Other Names: U-77,233, Ormaplatin (USAN)

CAS Registry Number: 62816-98-2

Molecular Formula: $C_6H_{14}Cl_4N_2Pt$ **M.W.**: 451.1

How Supplied: For injection, 50 mg, vial: supplied as a sterile freeze-dried product containing 50 mg of tetraplatin, 500 mg of mannitol, USP, and 90 mg of sodium chloride, USP in a 20 mL amber vial.

Solution Preparation: 50 mg/vial: Constitute with 10 mL of Water for Injection, USP. Each milliliter of resulting solution contains 5 mg of tetraplatin with 50 mg of mannitol, USP, and 9 mg of sodium chloride, USP, at a pH of 3.5 to 5.5.

Storage: Store the intact vials under refrigeration (2-8°C).

Stability: Shelf-life surveillance of the intact vials is ongoing. One lot was stable for at least four years at room temperature (22-25 °C). This lot was stable for at least one year at elevated temperature (50 °C).

> **CAUTION:** This single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

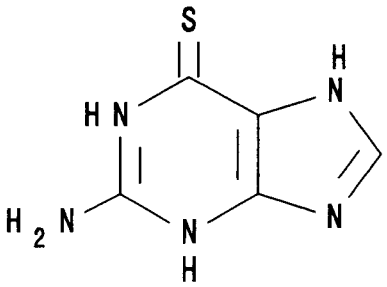
Reference:

1. Cheung YW, Cradock JC, Vishnuvajjala BR, and Flora, KP: Stability of cisplatin, iproplatin, carboplatin, and tetraplatin in commonly used intravenous solutions, Am J Hosp Pharm 44:124-130, 1987.

THIOGUANINE

NSC - 752

The following information applies to the investigational intravenous dosage form of thioguanine. For information regarding the commercially available dosage form (tablets), consult the package insert prepared by the Burroughs Wellcome Company.



Chemical Name: 6H-Purine-6-thione, 2-amino-1,7-dihydro-

Other Names: 6-Thioguanine, 6-TG, Tabloid®, Thioguanine (USAN)

CAS Registry Number: 154-42-7

Molecular Formula: $C_5H_5N_5S$ **M.W.:** 167.2

How Supplied: Sterile, 75 mg, vial: supplied as a lyophilized powder in 10 mL flint vials. Sufficient sodium hydroxide has been added to yield the sodium salt of thioguanine equivalent to 75 mg of thioguanine base.

Solution Preparation: 75 mg/vial (as thioguanine): When constituted with 5 mL of 0.9% Sodium Chloride Injection, USP, each milliliter of solution contains 15 mg of thioguanine and sodium hydroxide for adjustment to pH 11.0 to 12.0.

Storage: Store the intact vials at refrigeration temperature (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. The intact vials are stable for at least 4 years at refrigeration temperature (2-8 °C) and 3 years at room temperature (22-25 °C). The intact vials are stable for at least one year at elevated temperature (50 °C).

Constitution as recommended results in a solution which is stable for at least 24 hours under refrigeration (2-8 °C).

NOTE: Room temperature storage of constituted solutions may result in precipitate formation upon standing.

Further dilution in 500 mL of 5% Dextrose in 0.9% Sodium Chloride Injection, USP, results in a solution which is stable for at least 24 hours at room temperature or refrigeration temperature.

Admixture of 0.5 mEq of sodium bicarbonate per 75 mg of thioguanine to infusion solutions containing 1 mg/mL of thioguanine in either 5% Dextrose Injection, USP, or 0.9% Sodium Chloride Injection, USP, has been performed.

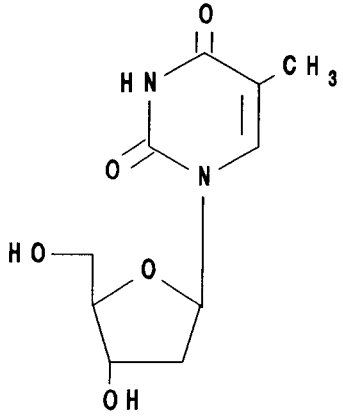
Addition of the sodium bicarbonate lowers the pH from about 11.5 to about 9.5. The admixture is physically and chemically stable for 8 hours both at room temperature and under refrigeration. Drug decomposition noted in this time interval was about 2 to 3% in the 0.9% Sodium Chloride Injection, USP, and about 6 to 8% in 5% Dextrose Injection, USP. Unacceptable losses occurred at 24 hours. A precipitate has also been noted during this time interval.

> **CAUTION**: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

THYMIDINE

NSC - 21548



Chemical Name: 2,4(1H,3H)-pyrimidinedione, 1-(2-deoxy-β-D-ribofuranosyl)-5-methyl-

CAS Registry Number: 50-89-5

Molecular Formula: $C_{10}H_{14}N_2O_5$ **M.W.**: 242.2

How Supplied: Injection, 3%, 500 mL infusion bottle, in 0.6% Sodium Chloride Injection: Each milliliter of solution contains 30 milligrams of thymidine (15 gms total per bottle). The total amount of sodium is 51.5 mEq per bottle. The solution is isotonic having approximately 300 milliosmoles per liter and has a pH of 4.5 to 7.5.

Storage: Store the infusion bottles at room temperature. Do not refrigerate or freeze thymidine infusion solutions because precipitation is likely to occur.

Stability: The 3% infusion solution is stable for at least four years at room temperature.

> **CAUTION**: Do not use 3% thymidine infusion solution unless it is sparkling clear and a vacuum is present.

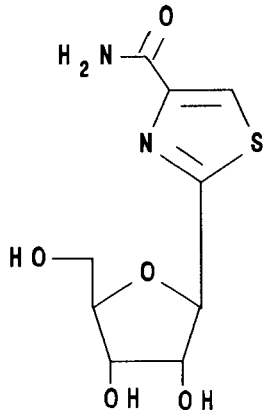
The addition of other medications to 3% thymidine injection is not advised because the chemical and physical effects have not been evaluated. Also, since the injection is formulated close to the limit of solubility for thymidine, addition of medication may cause a precipitate to form.

Route of Administration: Intravenous (by slow infusion)

> **NOTE**: The infusion bottle requires the use of a self-venting administration set. The use of an in-line filter does not affect the potency of this drug.

TIAZOFURIN

NSC - 286193



Chemical Name: 4-Thiazolecarboxamide, 2-β-D-ribofuranosyl-

Other Names: Riboxamide, TCAR, Tiazofurin (USAN)

CAS Registry Number: 60084-10-8

Molecular Formula: $C_9H_{12}N_2O_5S$ **M.W.:** 260.3

How Supplied: Sterile, 1 gm, vial: supplied as a white lyophilized powder with sodium hydroxide to adjust pH in a 20 mL flint vial.

Solution Preparation: 1 gm/vial: When constituted with 4.6 mL of Sterile Water for Injection, USP, each milliliter of the resulting solution contains 200 mg of tiazofurin with sodium hydroxide to adjust to pH 6 to 8.

Storage: Store the intact vials under refrigeration (2-8°C).

Stability: Intact vials are stable for 5 years when stored at room temperature (22-25 °C), and stable for at least one year when stored at elevated temperature (50 °C).

Constitution as recommended results in a solution which is chemically stable, exhibiting no decomposition for 7 days at room temperature while exposed to light.

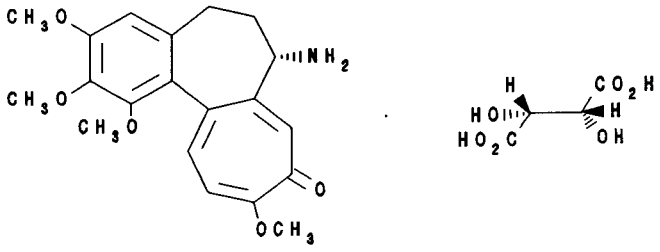
Further dilution in 5% Dextrose Injection, USP, and 0.9% Sodium Chloride Injection, USP, to a concentration of 1 mg/mL also resulted in solutions exhibiting no decomposition for 7 days at room temperature and exposed to light.

> **CAUTION**: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

TMCA

NSC - 36354



Chemical Name: Benzo[a]heptalen-9(5H)-one,7-amino-6,7-dihydro-1,2,3,10-tetramethoxy-,[R-(R*,R*)]-2,3-dihydroxybutanedioate (1:1)

Other Names: Trimethylcolchicinic acid, methyl ester, L-tartrate (1:1)

CAS Registry Number: 49720-72-1

Molecular Formula: $C_{20}H_{23}NO_5 \cdot C_4H_6O_6$ **M.W.:** 507.5

How Supplied: Capsules, 1 mg: Each opaque, pink capsule also contains lactose, silicon dioxide and Sterotex® (a hydrogenated vegetable fat). There are 100 capsules per bottle.

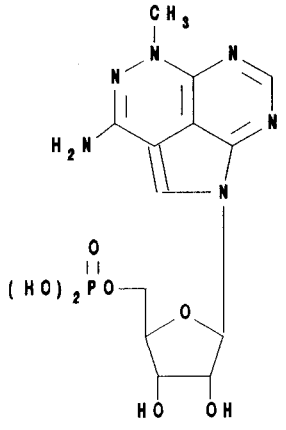
Storage: Store frozen in tightly sealed bottles.

Stability: Shelf-life surveillance of the capsules in intact bottles is ongoing.

Route of Administration: Oral

TRICIRIBINE PHOSPHATE

NSC - 280594



Chemical Name: 1,4,5,6,8-Pentaazaacenaphthylen-3-amine, 1,5-dihydro-5-methyl-1-(5-O-phosphono-β-D-ribofuranosyl)-

Other Names: TCN; Tricyclic Nucleoside 5'-Phosphate, TCN-P, Triciribine Phosphate (USAN)

CAS Registry Number: 61966-08-3

Molecular Formula: $C_{13}H_{17}N_6O_7P$ **M.W.:** 400.3

How Supplied: For Injection, 50 mg, vial: supplied as a white lyophilized powder with 100 mg of mannitol, USP, and sodium hydroxide to adjust pH, in 10 mL flint vials.

Solution Preparation: 50 mg/vial: When constituted with 2.5 mL of Sterile Water for Injection, USP, each milliliter contains 20 mg of triciribine phosphate, 40 mg of mannitol, USP, and sodium hydroxide to adjust to pH 6.0 to 7.5.

Storage: Refrigerate the intact vials (2-8°C).

Stability: Shelf-life surveillance of the intact vials is ongoing. The intact vials are stable for at least 2 years at room temperature (22-25 °C). The intact vials were found to be unstable when stored at elevated temperature (50 °C) for one year. The intact vials bear a "do not use after" date.

Constituted solutions of triciribine phosphate exhibit little or no decomposition for at least 24 hours at room temperature (22-25 °C).

Further dilution to a concentration of 1 mg/mL in 0.9% Sodium Chloride Injection, USP, or Lactated Ringer's Injection, USP, also results in solutions exhibiting little or no decomposition for at least 24 hours at room temperature. Dilution in 5% Dextrose Injection, USP, to a 1 mg/mL concentration resulted in about 3 to 4% decomposition over 24 hours at room temperature.

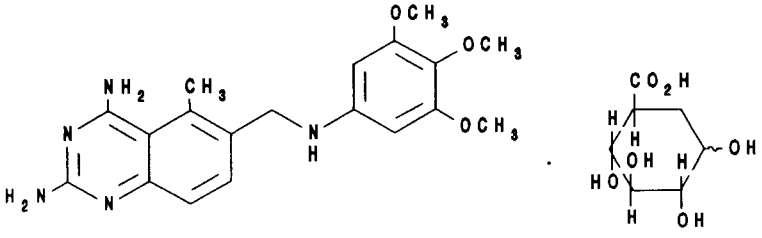
> **CAUTION**: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

TRIMETREXATE

NSC - 352122

The product described below is supplied by Warner-Lambert Company, Ann Arbor, Michigan, for clinical trials sponsored by the Division of Cancer Treatment, National Cancer Institute.



Chemical Name: 6-(((3,4,5-trimethoxyphenyl)amino)methyl)-5-methyl-2,4-quinazolinediamine, D-glucuronic acid

Other Names: TMTX, Trimetrexate (USAN)

CAS Registry Number: 52128-35-5

Molecular Formula: $C_{19}H_{23}N_5O_3 \cdot C_6H_{10}O_7$ **M.W.:** 564.0

How Supplied: For injection, 25 mg, vial: supplied as a pale greenish-yellow to tan colored lyophilized powder with glucuronic acid to form the glucuronate salt, in 6 mL flint vials.

Solution Preparation: 25 mg/vial: When constituted with 2 mL of Sterile Water for Injection, USP, each milliliter contains 12.5 mg of trimetrexate, present as the glucuronate salt. The pH of the constituted solution is 3.5 to 5.5.

Storage: Store the intact vials at room temperature.

Stability: Shelf-life surveillance of the intact vials is ongoing. Evaluation by Warner-Lambert has shown that trimetrexate is stable for at least 24 months at room temperature (22-25 °C).

When constituted as directed, the solution of trimetrexate is stable for up to 24 hours both at room temperature (22-25 °C) and under refrigeration (2-8 °C).

Further dilution to a concentration of 0.1 mg/mL in 5% Dextrose Injection, USP, results in a solution in which trimetrexate is stable both at room temperature and under refrigeration for at least 48 hours. At a concentration of 4 mg/mL in 5% Dextrose Injection, USP, trimetrexate is stable for 24 hours at room temperature or under refrigeration.

Exposure of both the constituted solution and the admixture in 5% Dextrose Injection, USP, to normal laboratory light during room temperature storage did not affect the stability of trimetrexate.

Trimetrexate may develop a precipitate in solutions above pH 5.

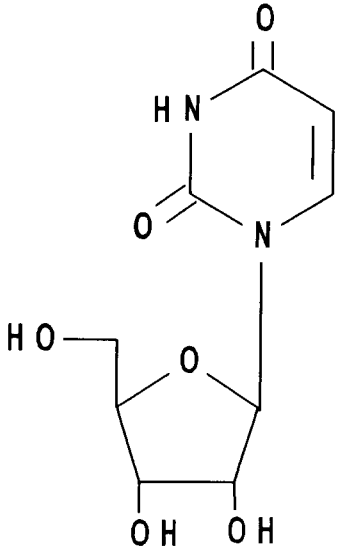
CAUTION: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

NOTE: Trimetrexate is incompatible with Sodium Chloride Injection, USP, and other chloride-containing solutions. Admixture with these solutions may result in precipitate formation.

Route of Administration: Intravenous

URIDINE

NSC - 20256



Chemical Name: 1-β-D-ribofuranosyluracil

CAS Registry Number: 58-96-8

Molecular Formula: $C_9H_{12}N_2O_6$ **M.W.:** 244.2

How Supplied: Injection, 10%, 500 mL infusion bottle: Each milliliter of solution contains 100 mg of uridine (50 gms total per bottle) in Water for Injection, USP. The solution has a pH of 4.5 to 6.5. The solution is isotonic having approximately 409 milliosmoles per liter.

Tablets, 1 gm: Each white, scored, film-coated tablet also contains the inert ingredients microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. There are 50 tablets per bottle.

Powder, 5 gm, oral: Each 15 mL amber vial with a tear-off aluminum seal contains 5 grams of Uridine to be mixed with an oral beverage.

Storage: Store the infusion bottles at room temperature (15-30 °C).

CAUTION: Do not refrigerate or freeze 10% uridine injection because precipitation may occur.

Storage: The tablets should be stored at room temperature.

Stability: The solution in intact bottles is stable for at least two years at room temperature. Shelf-life studies on the tablets in intact bottles are ongoing.

Route of Administration: Intravenous, oral

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