

Medication Guide
DUEXIS[®] (due ex is)
(ibuprofen and famotidine)
tablets

Read this Medication Guide before you start taking DUEXIS and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about DUEXIS?

DUEXIS contains ibuprofen [a nonsteroidal anti-inflammatory drug (NSAID)] and famotidine. NSAID-containing medicines, such as DUEXIS, may increase the chance of a heart attack or stroke that can lead to death. This chance increases:

- with longer use of NSAID medicines
- in people who have heart disease

NSAID-containing medicines, such as DUEXIS, should never be used right before or after a heart surgery called a coronary artery bypass graft (CABG).

NSAID-containing medicines, such as DUEXIS can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Ulcers and bleeding:

- can happen without warning symptoms
- may cause death

The chance of a person getting an ulcer or bleeding with NSAIDs increases with:

- taking medicines called steroid hormones (corticosteroids) and blood thinners (anticoagulants)
- longer use of the NSAID
- smoking
- drinking alcohol
- older age
- having poor health

NSAID-containing medicines, such as DUEXIS, should only be used:

- exactly as prescribed
- at the lowest dose possible for your treatment
- for the shortest time needed

What are Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?

NSAID medicines are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions such as:

- different types of arthritis (rheumatoid arthritis and osteoarthritis)

Who should not take a Non-Steroidal Anti-Inflammatory Drug (NSAID)?

Do not take an NSAID medicine:

- If you had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAID medicine
- For pain right before or after heart bypass surgery

Tell your healthcare provider:

- about all of your medical conditions.
- about all of the medicines you take. NSAIDs and some other medicines can interact with each other and cause serious side effects. **Keep a list of your medicines to show to your healthcare provider and pharmacist.**
- if you are pregnant. **NSAID medicines should not be used by pregnant women late in their pregnancy.**
- if you are breastfeeding. **Talk to your healthcare provider.**

What are the possible side effects of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?

Serious side effects include:	Other side effects include:
<ul style="list-style-type: none"> • heart attack • stroke • high blood pressure • heart failure from body swelling (fluid retention) • kidney problems including kidney failure • bleeding and ulcers in the stomach and intestine • low red blood cells (anemia) • life-threatening skin reactions • life-threatening allergic reactions • liver problems including liver failure • asthma attacks in people who have asthma 	<ul style="list-style-type: none"> • stomach pain • constipation • diarrhea • gas • heartburn • nausea • vomiting • dizziness

Get emergency help right away if you have any of the following symptoms:

- | | |
|--|---|
| <ul style="list-style-type: none"> • shortness of breath or trouble breathing • chest pain | <ul style="list-style-type: none"> • weakness in one part or side of your body • slurred speech • swelling of the face or throat |
|--|---|

Stop your NSAID medicine and call your healthcare provider right away if you have any of the following symptoms:

<ul style="list-style-type: none"> • nausea • more tired or weaker than usual • itching • your skin or eyes look yellow • stomach pain • flu-like symptoms • vomit blood 	<ul style="list-style-type: none"> • there is blood in your bowel movement or it is black and sticky like tar • unusual weight gain • skin rash or blisters with fever • swelling of the arms and legs, hands and feet
---	--

These are not all the side effects with NSAID medicines. Talk to your healthcare provider or pharmacist for more information about NSAID medicines.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Other information about Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

- Aspirin is an NSAID but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines.
- Some of these NSAID medicines are sold in lower doses without a prescription (over-the-counter). Talk to your healthcare provider before using over-the-counter NSAIDs for more than 10 days.

NSAID medicines that need a prescription

Generic Name	Requires Prescription
Celecoxib	Celebrex
Diclofenac	Cataflam, Voltaren, Arthrotec (combined with misoprostol)
Difunisal	Dolobid
Etodolac	Lodine, Lodine XL
Fenoprofen	Nalfon, Nalfon 200
Flurbiprofen	Ansaid
Ibuprofen	Motrin, Tab-Profen, Vicoprofen (combined with hydrocodone), Combunox (combined with oxycodone), DUEXIS (combined with famotidine)
Indomethacin	Indocin, Indocin SR, Indo-Lemmon, Indomethagan
Ketoprofen	Orudis, Orudis KT, Oruvail
Ketorolac	Toradol
Mefanamic Acid	Ponstel
Meloxicam	Mobic
Nabumetone	Relafen
Naproxen	Naprosyn, Anaprox, Anaprox DS, Prevacid NapraPAC (Prevacid copackaged with Naprosyn), Vimovo (combined with esomeprazole)
Oxaprozin	Daypro
Enteric coated naproxen	EC-Naproxen, Naprelan
Piroxicam	Feldene
Sulindac	Clinoril
Tolmetin	Tolectin, Tolectin DS, Tolectin 600

What is DUEXIS?

DUEXIS contains 2 medicines:

1. Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID). Please read the above information regarding the benefits and risks of NSAIDs, including ibuprofen, a component of DUEXIS.
2. Famotidine is a histamine 2 (H₂)-receptor antagonist, a medicine that may help reduce stomach acid.

DUEXIS is a prescription medicine used to:

- relieve signs and symptoms of rheumatoid arthritis and osteoarthritis

- decrease the risk of developing ulcers of the stomach and upper intestines (upper gastrointestinal ulcers) in people who are taking ibuprofen for rheumatoid arthritis and osteoarthritis. DUEXIS was studied mostly in people less than 65 years of age and who did not have a prior history of ulcers of the stomach and upper intestines.

It is not known if DUEXIS is safe or effective in children.

Who should not take DUEXIS?

Do not take DUEXIS:

- If you had an asthma attack, hives, or other allergic reaction after taking aspirin or other NSAID medicine.
- For pain right before or after heart bypass surgery.
- If you are in the late stages of pregnancy (after 30 weeks of pregnancy).
- If you are allergic to any other histamine 2 (H₂)-receptor antagonist.

What should I tell my healthcare provider before taking DUEXIS?

Before you take DUEXIS, tell your healthcare provider if you:

- have high blood pressure (hypertension)
- have heart problems
- have a history of stomach ulcers
- have or had bleeding problems
- have liver or kidney problems
- have ulcerative colitis or Crohn's disease (inflammatory bowel disease or IBD)
- have any other medical conditions
- are pregnant or plan to become pregnant. DUEXIS should not be used by pregnant women late their pregnancy. **See "What is the most important information I should know about DUEXIS?"**
- are breast-feeding or plan to breast-feed. DUEXIS can pass into your milk and may harm your baby. You should not breast-feed while taking DUEXIS. Talk to your healthcare provider about the best way to feed your baby if you take DUEXIS.

Tell your healthcare provider about all of the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements. Since DUEXIS contains ibuprofen, talk to your healthcare provider before taking any other NSAID containing products.

Using DUEXIS with other medicines can cause serious side effects. DUEXIS may affect the way other medicines work and other medicines may affect how DUEXIS works.

Especially, tell your doctor if you take:

- Aspirin
- Warfarin (Coumadin)

How should I take DUEXIS?

- Take DUEXIS exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how many DUEXIS to take and when to take them.
- Do not stop DUEXIS without first talking to your healthcare provider.
- Swallow DUEXIS tablets whole. Do not crush, split or chew DUEXIS tablets.
- If you forget to take a dose of DUEXIS, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose. Take the next dose on time. Do not take 2 doses at one time to make up for a missed dose.
- If you take too much DUEXIS, tell your healthcare provider or go to the nearest hospital emergency room right away.

If you take more DUEXIS than your doctor recommends, call your Poison Control Center at 1-800-222-1222.

- Your doctor may do certain tests from time to time to check you for side effects of DUEXIS.

What are the possible side effects of DUEXIS?

DUEXIS may cause serious side effects.

See “What is the most important information I should know about DUEXIS?”

- **Stroke or Heart Attack.** If you have heart disease you may be at risk for a heart attack or stroke while taking DUEXIS. Call your healthcare provider or get medical help right away if you have any of these signs and symptoms:

Signs and symptoms of a Stroke

- numbness or weakness of the face, arm or leg, especially on one side of the body
- sudden confusion, trouble speaking or understanding
- sudden trouble seeing in one or both eyes
- sudden trouble walking, dizziness, loss of balance or coordination
- sudden, severe headache

Signs and symptoms of a Heart Attack

- chest discomfort in the center of your chest that lasts for more than few minutes, or that goes away or comes back
 - chest discomfort that feels like uncomfortable pressure or squeezing.
 - chest fullness or pain
 - pain or discomfort in your arms, back, neck, jaw or stomach
 - shortness of breath with or without chest discomfort
 - break out in a cold sweat
 - nausea or vomiting
- **New or worsening high blood pressure (hypertension).** Your healthcare provider should check your blood pressure while you are taking DUEXIS.
 - **Heart problems** such as congestive heart failure. Tell your healthcare provider about any swelling of your body, hands or feet, sudden weight gain or trouble breathing.
 - **Active bleeding.** Tell your doctor if you have signs of active bleeding including:
 - passing black sticky bowel movements (stools)
 - having bloody diarrhea
 - vomiting or coughing up blood or dark particles that look like coffee grounds
 - **Kidney problems.** Long term use of NSAIDS, including ibuprofen which is a medicine in DUEXIS can cause kidney problems. Your healthcare provider should do blood test to check your kidneys.
 - **Serious allergic reactions.** Tell your healthcare provider or get medical help right away if you get:
 - swelling of your lips, tongue, or face
 - throat tightness
 - rash
 - problems breathing or swallowing
 - **Serious skin reactions.** NSAIDS, including ibuprofen which is a medicine in DUEXIS can cause a serious skin reaction called Stevens-Johnson Syndrome, toxic epidermal necrolysis or other serious skin reactions that may affect any part of your body. These

serious skin reactions may be life threatening and you may need to be treated in a hospital. Stop taking DUEXIS and call your healthcare provider right away if you have any of these symptoms:

- skin rash or acne
- dry skin
- itching
- blisters on your skin
- blisters or sores in your mouth
- peeling of your skin
- fever
- muscle or joint aches
- redness or swelling of your face, hands, or soles of your feet

- **Liver problems.** Tell your healthcare provider right away if you have any of these following symptoms of liver problems:

- dark (tea colored) urine
- yellowing of your skin or whites of your eyes
- light-colored bowel movements (stools)
- fever
- nausea (feeling sick to your stomach)
- feel unwell or like you have the flu
- pain or tenderness on your right side below your ribs
- tiredness
- loss of appetite

- **Low red blood cell count (anemia).** Symptoms of anemia include shortness of breath and tiredness.

- **Meningitis.** Ibuprofen, one of the medicines in DUEXIS may cause meningitis, a serious brain problem. Call your healthcare provider right away if you have any of the following symptoms of meningitis:

- headache
- fever
- nausea
- vomiting
- stiff neck
- rash
- unusual sensitivity to light
- muscle pains
- chills
- confusion
- drowsiness

- **Eye problems.** Tell your healthcare provider if you develop blurred or decreased vision, changes in color vision, or any other problems with your eyes.

- nausea
- constipation
- diarrhea
- upper stomach (abdominal) pain
- vomiting
- throat irritation, pain or swelling
- back pain

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of DUEXIS. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store DUEXIS?

- Store DUEXIS at 59°F to 86°F (15°C to 30°C).
- Keep DUEXIS in the original container and keep the bottle tightly closed.
- Keep DUEXIS dry.

Keep DUEXIS and all medicines out of the reach of children.

General information about DUEXIS.

Medicines are sometimes prescribed for purposes other than those listed in this Medication Guide. Do not use DUEXIS for a condition for which it was not prescribed. Do not give DUEXIS to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about DUEXIS. If you would like more information, ask your healthcare provider. You can ask your healthcare provider or pharmacist for information that is written for healthcare professionals.

For more information, go to www.DUEXIS.com or call 1-866-479-6742

What are the ingredients in DUEXIS?

Active ingredients: ibuprofen and famotidine

Inactive ingredients: microcrystalline cellulose, anhydrous lactose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, purified water, povidone, titanium dioxide, polyethylene glycol, polysorbate 80, polyvinyl alcohol, talc, FD&C Blue #2/Indigo Carmine Aluminum Lake and FD&C Blue #1/Brilliant Blue FDF Aluminum Lake

This Medication Guide has been approved by the U.S. Food and Drug Administration.

**Horizon Pharma USA, Inc.
1033 Skokie Blvd. Ste. 355
Northbrook, Illinois 60062**

April 2011