Medication Guide
EXALGO® (eks-al-goh)
(hydromorphone hydrochloride extended-release) Tablets, CII

EXALGO is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to treat moderate to severe around-the-clock pain, in people who are already regularly using opioid pain medicine.

Important information about EXALGO:

- Get emergency help right away if you take too much EXALGO (overdose). EXALGO overdose can cause life threatening breathing problems that can lead to death.
- Never give anyone else your EXALGO. They could die from taking it. Store EXALGO away from children and in a safe place to prevent stealing or abuse. Selling or giving away EXALGO is against the law.

Do not take EXALGO if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before taking EXALGO, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- allergy to hydromorphone or sulfites
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** EXALGO may harm your unborn baby.
- **breastfeeding.** EXALGO passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

When taking EXALGO:

- Do not change your dose. Take EXALGO exactly as prescribed by your healthcare provider.
- Take your prescribed dose at the same time every day. Do not take more than your prescribed dose in 24 hours. If you miss a dose, do not take EXALGO. Take your next dose at your usual time the next day.
- Swallow EXALGO whole. Do not cut, break, chew, crush, dissolve, or inject EXALGO.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking EXALGO without talking to your healthcare provider.**
- EXALGO is contained in a hard tablet shell that you may see in your bowel movement; this is normal.
- After you stop taking EXALGO, flush any unused tablets down the toilet.

While taking EXALGO Do Not:

- Drive or operate heavy machinery, until you know how EXALGO affects you. EXALGO can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

The possible side effects of EXALGO are:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, or you are feeling faint.

These are not all the possible side effects of EXALGO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Distributed by: Mallinckrodt Brand Pharmaceuticals, Inc., Hazelwood, MO 63042 USA, www.Exalgo.com or call 1-800-778-7898

Mallinckrodt

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Medication Guide

EMBEDA® (im-bed-a)
(morphine sulfate and naltrexone hydrochloride extended-release) Capsules, CII

EMBEDA is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to treat moderate to severe around-the-clock pain.

Important information about EMBEDA:

- Get emergency help right away if you take too much EMBEDA (overdose). EMBEDA overdose can cause life threatening breathing problems that can lead to death.
- Never give anyone else your EMBEDA. They could die from taking it. Store EMBEDA away from children and in a safe place to prevent stealing or abuse. Selling or giving away EMBEDA is against the law.

Do not take EMBEDA if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before taking EMBEDA, tell your healthcare provider if you have a history of:

- head injury, seizures
- problems urinating
- liver, kidney, thyroid problems
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** EMBEDA may harm your unborn baby.
- **breastfeeding.** EMBEDA passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

When taking EMBEDA:

- Do not change your dose. Take EMBEDA exactly as prescribed by your healthcare provider.
- Take your prescribed dose at the same time every day. Do not take more than your prescribed dose in 24 hours. If you miss a dose, take EMBEDA as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at the same time unless your healthcare provider tells you to.
- Swallow EMBEDA whole. Do not cut, break, chew, crush, dissolve, or inject EMBEDA. You should not receive EMBEDA through a nasogastric tube or gastric tube (stomach tube).
- If you cannot swallow EMBEDA capsules, see the detailed Instructions for Use.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking EMBEDA without talking to your healthcare provider.**
- After you stop taking EMBEDA, flush any unused capsules down the toilet.

While taking EMBEDA Do Not:

- Drive or operate heavy machinery, until you know how EMBEDA affects you. EMBEDA can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

The possible side effects of EMBEDA are:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, or you are feeling faint.

These are not all the possible side effects of EMBEDA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Manufactured for: King Pharmaceuticals, Inc., 501 Fifth Street, Bristol, TN 37620 by: Actavis Elizabeth LLC, 200 Elmora Avenue, Elizabeth, NJ 07207, www.embeda.com or call 1-800-438-1985

Instructions For Use
EMBEDA® (im-bed-a)
(morphine sulfate and naltrexone hydrochloride extended-release) Capsules, CII

- If you cannot swallow EMBEDA® capsules, tell your healthcare provider. There may be another way to take EMBEDA® that may be right for you. If your doctor tells you that you can take EMBEDA® using this other way, follow these steps:

EMBEDA® can be opened and the pellets inside the capsule can be sprinkled over apple sauce, as follows:

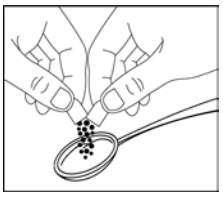

Figure 1

- Open the EMBEDA® capsule and sprinkle the pellets over approximately one tablespoon of apple sauce *(Figure 1)*.

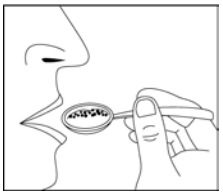

Figure 2

- Swallow all of the apple sauce and pellets right away. Do not save any of the apple sauce and pellets for another dose *(Figure 2)*.

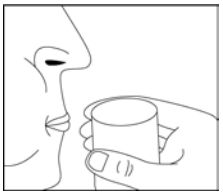

Figure 3

- Rinse your mouth to make sure you have swallowed all of the pellets. Do not chew the pellets *(Figure 3)*.

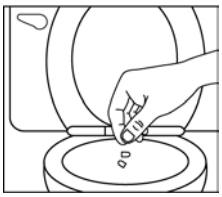

Figure 4

- Flush the empty capsule down the toilet right away *(Figure 4)*.

- You should not receive EMBEDA® through a nasogastric tube or gastric tube (stomach tube).

Medication Guide
DURAGESIC® (Dur-ah-GEE-zik)
(fentanyl) Transdermal System, CII

DURAGESIC® is:
- A strong prescription pain medicine that contains an opioid (narcotic) that is used to treat moderate to severe around-the-clock pain, in people who are already regularly using opioid pain medicine.

Important information about DURAGESIC®:
- Get emergency help right away if you use too much DURAGESIC® (overdose). DURAGESIC® overdose can cause life threatening breathing problems that can lead to death.
- Never give anyone else your DURAGESIC®. They could die from using it. Store DURAGESIC® away from children and in a safe place to prevent stealing or abuse. Selling or giving away DURAGESIC® is against the law.

Do not use DURAGESIC® if you have:
- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before applying DURAGESIC®, tell your healthcare provider if you have a history of:
- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you:
- have a fever
- **are pregnant or planning to become pregnant.** DURAGESIC® may harm your unborn baby.
- **are breastfeeding.** DURAGESIC® passes into breast milk and may harm your baby.
- are taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

When using DURAGESIC®:
- Do not change your dose. Apply DURAGESIC® exactly as prescribed by your healthcare provider.
- See the detailed Instructions for Use for information about how to apply and dispose of the DURAGESIC® patch.
- Do not wear more than 1 patch at the same time unless your healthcare provider tells you to.
- **Call your healthcare provider if the dose you are using does not control your pain.**
- **Do not stop using DURAGESIC® without talking to your healthcare provider.**

While using DURAGESIC® Do Not:
- Take hot baths or sunbathe, use hot tubs, saunas, heating pads, electric blankets, heated waterbeds, or tanning lamps, or engage in exercise that increases your body temperature. These can cause an overdose that can lead to death.
- Drive or operate heavy machinery, until you know how DURAGESIC® affects you. DURAGESIC® can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

The possible side effects of DURAGESIC® are:
- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain, itching, redness, or rash where the patch is applied. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:
- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, or you are feeling faint.

These are not all the possible side effects of DURAGESIC®. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Manufactured by: Alza Corporation, Vacaville, CA 95688; Manufactured for: Janssen Pharmaceuticals, Inc. Titusville, NJ 08560, www.Duragesic.com or call 1-800-526-7736

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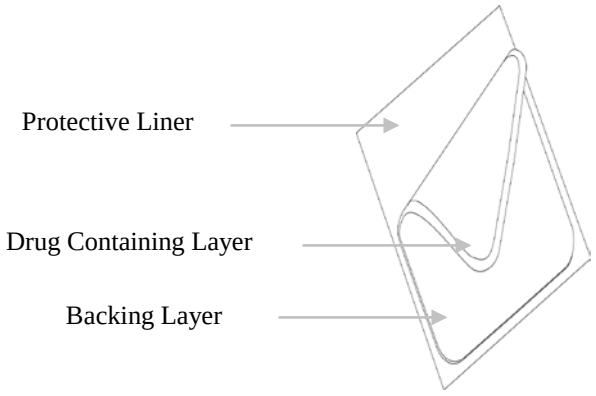
DURAGESIC® (Dur-ah-GEE-zik)
(Fentanyl Transdermal System) CII

Instructions for Applying a DURAGESIC® patch



Before Applying DURAGESIC®

- **Each DURAGESIC® patch is sealed in its own protective pouch. Do not remove a DURAGESIC® patch from the pouch until you are ready to use it.**
- **Do not use a DURAGESIC® patch if the pouch seal is broken or the patch is cut, damaged or changed in any way.**
- **DURAGESIC® patches are available in 5 different doses and patch sizes. Make sure you have the right dose patch or patches that have been prescribed for you.**

Applying a DURAGESIC® Patch

1. **Skin Areas Where the DURAGESIC® Patch May Be Applied:**

   For adults:

   - Put the patch on the chest, back, flank (sides of the waist), or upper arm in a place where there is no hair (see Figures 1-4).

   For children (and adults with mental impairment):

   - **Put the patch on the upper back (see Figure 2).** This will lower the chances that the child will remove the patch and put it in their mouth.

   For adults and children

   - Do not put a DURAGESIC® patch on skin that is very oily, burned, broken out, cut, irritated, or damaged in any way.
   - Avoid sensitive areas or those that move around a lot. If there is hair, **do not shave (shaving irritates the skin)**. Instead, clip hair as close to the skin as possible (see Figure 5).
   - **Talk to your doctor if you have questions about skin application sites.**

2. **Prepare to Apply a DURAGESIC® Patch:**

   - Choose the time of day that is best for you to apply DURAGESIC®. Change it at about the same time of day (3 days or 72 hours after you apply the patch) or as directed by your doctor.
   - Do not wear more than one DURAGESIC® patch at a time unless your doctor tells you to do so. Before putting on a new DURAGESIC® patch, remove the patch you have been wearing.
   - Clean the skin area with clear water **only**. **Pat skin completely dry.** Do not use anything on the skin such as soaps, lotions, oils, or alcohol before the patch is applied.

Figure 1

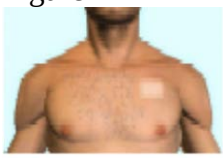


Figure 2

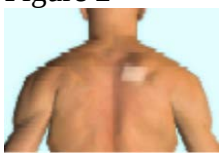


Figure 3

Figure 4

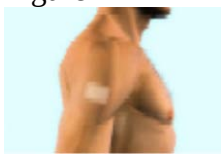
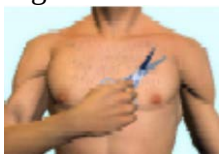


Figure 5



3. **Open the Pouch:** Fold and tear at slit, or cut at slit taking care so as not to cut the patch, and remove the DURAGESIC® patch. Each DURAGESIC® patch is sealed in its own protective pouch. Do not remove the DURAGESIC® patch from the pouch until you are ready to use it (see Figure 6).

Figure 6

4. **Peel:** Peel off both parts of the protective liner from the patch. Each DURAGESIC® patch has a clear plastic backing that can be peeled off in two pieces. This covers the sticky side of the patch. Carefully peel this backing off. Throw the clear plastic backing away. **Touch the sticky side of the DURAGESIC® patch as little as possible** (see Figure 7).

Figure 7

5. **Press:** Press the patch onto the chosen skin site **with the palm of your hand and hold there for at least 30 seconds** (see Figure 8). Make sure it sticks well, especially at the edges.

Figure 8

- DURAGESIC® may not stick to all patients. You need to check the patches often to make sure that they are sticking well to the skin.
- If the patch falls off right away after applying, throw it away and put a new one on at a different skin site (see Disposing a DURAGESIC® Patch).
- If you have a problem with the patch not sticking
    - Apply first aid tape only to the edges of the patch.
    - If you continue to have problems with the patch sticking, you may cover the patch with Bioclusive™ or Tegaderm™. These are special see-through adhesive dressings. **Never cover a DURAGESIC® patch with any other bandage or tape.** Remove the backing from the Bioclusive™ or Tegaderm™ dressing and place it carefully over the DURAGESIC® patch, smoothing it over the patch and your skin.
- **If your patch falls off later, but before 3 days (72 hours) of use, discard it properly (see Disposing a DURAGESIC® patch) and put a new one on at a different skin site. Be sure to let your doctor know that this has happened, and do not replace the new patch until 3 days (72 hours) after you put it on (or as directed by your doctor).**

6. Wash your hands when you have finished applying a DURAGESIC® patch.

7. Remove a DURAGESIC® patch after wearing it for 3 days (72 hours) (see "Disposing a DURAGESIC® Patch"). Choose a **different** place on the skin to apply a new DURAGESIC® patch and repeat Steps 2 through 6.

   Do not apply the new patch to the same place as the last one.

Water and DURAGESIC®

- You can bathe, swim or shower while you are wearing a DURAGESIC® patch. If the patch falls off before 3 days (72 hours) after application, discard it properly (see Disposing a DURAGESIC® Patch) and put a new one on at a different skin site. Be sure to let your doctor know that this has happened, and do not replace the new patch until 3 days (72 hours) after you put it on (or as directed by your doctor).

Disposing a DURAGESIC® Patch

- Fold the used DURAGESIC® patch in half so that the sticky side sticks to itself (Figure 9). **Flush the used DURAGESIC® down the toilet right away** (Figure 10). **A used DURAGESIC® patch CAN be VERY dangerous for or even lead to death in babies, children, pets, and adults who have not been prescribed DURAGESIC®.**
- Throw away any DURAGESIC® patches that are left over from your prescription as soon as they are no longer needed. Remove the leftover patches from their protective pouch and remove the protective liner. **Fold the patches in half with the sticky sides together, and flush the patches down the toilet.** Do not flush the pouch or the protective liner down the toilet. These items can be thrown away in a trashcan.

Figure 9

Figure 10

Bioclusive™ is a trademark of Ethicon, Inc.

Tegaderm™ is a trademark of 3M

Rx Only

Manufactured by:
ALZA Corporation
Vacaville, CA 95688

Manufactured for:
Janssen Pharmaceuticals, Inc.
Titusville, NJ 08560

October 2011 Insert new code

Medication Guide

KADIAN® (key-dee-uhn)

(morphine sulfate extended-release) Capsules, CII

KADIAN® is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to treat moderate to severe around-the-clock pain.

Important information about KADIAN®:

- Get emergency help right away if you take too much KADIAN® (overdose). KADIAN® overdose can cause life threatening breathing problems that can lead to death.
- Never give anyone else your KADIAN®. They could die from taking it. Store KADIAN® away from children and in a safe place to prevent stealing or abuse. Selling or giving away KADIAN® is against the law.

Do not take KADIAN® if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before taking KADIAN®, tell your healthcare provider if you have a history of:

- head injury, seizures
- problems urinating
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.
- liver, kidney, thyroid problems
- pancreas or gallbladder problems

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** KADIAN® may harm your unborn baby.
- **breastfeeding.** KADIAN® passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

When taking KADIAN®:

- Do not change your dose. Take KADIAN® exactly as prescribed by your healthcare provider.
- Take your prescribed dose at the same time every day. Do not take more than your prescribed dose in 24 hours. If you miss a dose, take KADIAN® as soon as possible and then take your next dose 12 or 24 hours later as directed by your healthcare provider. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule.
- Swallow KADIAN® whole. Do not cut, break, chew, crush, dissolve, or inject KADIAN®.
- If you cannot swallow KADIAN® capsules, see the detailed Instructions for Use.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking KADIAN® without talking to your healthcare provider.**
- After you stop taking KADIAN®, flush any unused capsules down the toilet.

While taking KADIAN® Do Not:

- Drive or operate heavy machinery, until you know how KADIAN® affects you. KADIAN® can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

The possible side effects of KADIAN® are:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, or you are feeling faint.

These are not all the possible side effects of KADIAN®. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Distributed by: Actavis Kadian LLC, 60 Columbia Rd., Bldg. B, Morristown, NJ 07960 USA, www.KADIAN.com or call -1-888-496-3082

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issue: July 2012

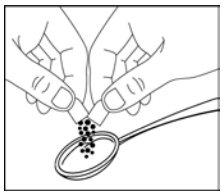
Instructions For Use

KADIAN® (key-dee-uhn)

(morphine sulfate extended-release) Capsules, CII

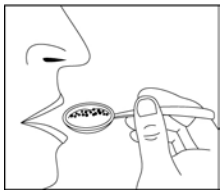
- If you cannot swallow KADIAN® capsules, tell your healthcare provider. There may be another way to take KADIAN® that may be right for you. If your doctor tells you that you can take KADIAN® using this other way, follow these steps:

KADIAN® can be opened and the pellets inside the capsule can be sprinkled over apple sauce, as follows:



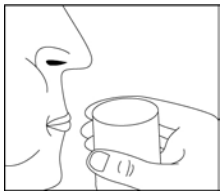
- Open the KADIAN® capsule and sprinkle the pellets over approximately one tablespoon of apple sauce *(Figure 1)*.

Figure 1



- Swallow all of the apple sauce and pellets right away. Do not save any of the apple sauce and pellets for another dose *(Figure 2)*.

Figure 2



- Rinse your mouth to make sure you have swallowed all of the pellets. Do not chew the pellets *(Figure 3).*

Figure 3

- Flush the empty capsule down the toilet right away *(Figure 4).*

Figure 4

You should not receive KADIAN® through a nasogastric tube.

Medication Guide
AVINZA® (ah-ven-zah)
(morphine sulfate extended-release) Capsules, CII

AVINZA is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to treat moderate to severe around-the-clock pain.

Important information about AVINZA:

- Get emergency help right away if you take too much AVINZA (overdose). AVINZA overdose can cause life threatening breathing problems that can lead to death.
- Never give anyone else your AVINZA. They could die from taking it. Store AVINZA away from children and in a safe place to prevent stealing or abuse. Selling or giving away AVINZA is against the law.

Do not take AVINZA if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before taking AVINZA, tell your healthcare provider if you have a history of:

- head injury, seizures
- problems urinating
- liver, kidney, thyroid problems
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** AVINZA may harm your unborn baby.
- **breastfeeding.** AVINZA passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

When taking AVINZA:

- Do not change your dose. Take AVINZA exactly as prescribed by your healthcare provider.
- Take 1 dose once a day at the same time every day. Do not take more than 1 dose in 24 hours. If you miss a dose, do not take AVINZA. Take your next dose at your usual time the next day.
- Swallow AVINZA whole. Do not cut, break, chew, crush, dissolve, or inject AVINZA.
- If you cannot swallow AVINZA capsules, see the detailed Instructions for Use.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking AVINZA without talking to your healthcare provider.**
- After you stop taking AVINZA, flush any unused capsules down the toilet.

While taking AVINZA Do Not:

- Drive or operate heavy machinery, until you know how AVINZA affects you. AVINZA can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

The possible side effects of AVINZA are:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, or you are feeling faint.

These are not all the possible side effects of AVINZA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Manufactured for: King Pharmaceuticals, Inc., Bristol, TN 37620 by: Alkermes Pharma Ireland Limited", Athlone, Ireland, www.avinza.com or call 1-800-438-1985

Reference ID: 3155455

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Instructions For Use
AVINZA ® (ah-ven-zah)
(morphine sulfate extended-release) Capsules, CII

- If you cannot swallow AVINZA ® capsules, tell your healthcare provider. There may be another way to take AVINZA ® that may be right for you. If your doctor tells you that you can take AVINZA® using this other way, follow these steps:

AVINZA® can be opened and the pellets inside the capsule can be sprinkled over apple sauce, as follows:

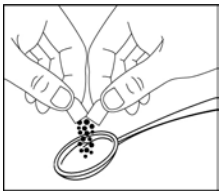


Figure 1

- Open the AVINZA® capsule and sprinkle the pellets over approximately one tablespoon of apple sauce *(Figure 1)*.

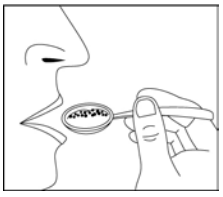


Figure 2

- Swallow all of the apple sauce and pellets right away. Do not save any of the apple sauce and pellets for another dose *(Figure 2)*.

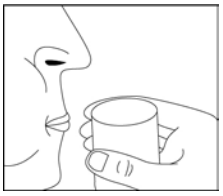


Figure 3

- Rinse your mouth to make sure you have swallowed all of the pellets. Do not chew the pellets *(Figure 3)*.

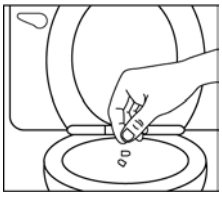


Figure 4

- Flush the empty capsule down the toilet right away *(Figure 4)*.

You should not receive AVINZA ® through a nasogastric tube or gastric tube (stomach tube).

Medication Guide
DOLOPHINE® (DOL-o-feen)
(methadone hydrochloride) Tablets, CII

DOLOPHINE is:

- A strong prescription pain medicine that contains methadone, an opioid (narcotic) that is used to treat moderate to severe around-the-clock pain.
- Used to manage drug addiction.

Important information about DOLOPHINE:

- Get emergency help right away if you take too much DOLOPHINE (overdose). DOLOPHINE overdose can cause life threatening breathing problems that can lead to death.
- Never give anyone else your DOLOPHINE. They could die from taking it. Store DOLOPHINE away from children and in a safe place to prevent stealing or abuse. Selling or giving away DOLOPHINE is against the law.

Do not take DOLOPHINE if you have:

- Severe asthma, trouble breathing, or other lung problems.
- A bowel blockage or have narrowing of the stomach or intestines.

Before taking DOLOPHINE, tell your healthcare provider if you have a history of:

- head injury, seizures
- problems urinating
- heart, liver, kidney, thyroid problems
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** DOLOPHINE may harm your unborn baby.
- **breastfeeding.** DOLOPHINE passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

When taking DOLOPHINE:

- Do not change your dose. Take DOLOPHINE exactly as prescribed by your healthcare provider.
- Do not take more than your prescribed dose in 24 hours. If you take DOLOPHINE for pain and miss a dose, take DOLOPHINE as soon as possible and then take your next dose 8 or 12 hours later as directed by your healthcare provider. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule.
- If you take DOLOPHINE for opioid addiction, take your next dose the following day as scheduled. Do not take extra doses. Taking more than the prescribed dose may cause you to overdose because DOLOPHINE builds up in your body over time.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking DOLOPHINE without talking to your healthcare provider.**
- After you stop taking DOLOPHINE, flush any unused tablets down the toilet.

While taking DOLOPHINE Do Not:

- Drive or operate heavy machinery, until you know how DOLOPHINE affects you. DOLOPHINE can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

The possible side effects of DOLOPHINE are:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, or you are feeling faint.

These are not all the possible side effects of DOLOPHINE. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov.**

Manufactured by: Roxane Laboratories, Inc., Columbus, Ohio 43216, www.Roxane.com, or call 1-800-962-8364

Boehringer Ingelheim
Roxane Laboratories

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

Issue: July 2012

Reference ID: 3155455

Medication Guide

OXYCONTIN® (ox-e-KON-tin)
(oxycodone hydrochloride controlled-release) Tablets, CII

OXYCONTIN is:
- A strong prescription pain medicine that contains an opioid (narcotic) that is used to treat moderate to severe around-the-clock pain.

Important information about OXYCONTIN:
- Get emergency help right away if you take too much OXYCONTIN (overdose). OXYCONTIN overdose can cause life-threatening breathing problems that can lead to death.
- Never give anyone else your OXYCONTIN. They could die from taking it. Store OXYCONTIN away from children and in a safe place to prevent stealing or abuse. Selling or giving away OXYCONTIN is against the law.

Do not take OXYCONTIN if you have:
- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before taking OXYCONTIN, tell your healthcare provider if you have a history of:
- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:
- **pregnant or planning to become pregnant.** OXYCONTIN may harm your unborn baby.
- **breastfeeding.** OXYCONTIN passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

When taking OXYCONTIN:
- Do not change your dose. Take OXYCONTIN exactly as prescribed by your healthcare provider.
- Take each dose every 12 hours at the same time every day. If you miss a dose, take OXYCONTIN as soon as possible and then take your next dose 12 hours later. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take more than 1 dose in 12 hours.
- Swallow OXYCONTIN whole. Do not cut, break, chew, crush, dissolve, or inject OXYCONTIN.
- OXYCONTIN should be taken 1 tablet at a time. Do not pre-soak, lick, or wet the tablet before placing in your mouth.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking OXYCONTIN without talking to your healthcare provider.**
- After you stop taking OXYCONTIN, flush any unused tablets down the toilet.

While taking OXYCONTIN Do Not:
- Drive or operate heavy machinery, until you know how OXYCONTIN affects you. OXYCONTIN can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

The possible side effects of OXYCONTIN are:
- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:
- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, or you are feeling faint.

These are not all the possible side effects of OXYCONTIN. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Manufactured by: Purdue Pharma L.P., Stamford, CT 06901-3431, **www.purduepharma.com or call 1-888-726-7535**

This Medication Guide has been approved by the U.S. Food and Drug Administration.
Issue: June 2012

OXYCONTIN® CII
(OXYCODONE HCl CONTROLLED-RELEASE) TABLETS

Medication Guide

BUTRANS® (BYOO-trans)
(buprenorphine) Transdermal System, CIII

BUTRANS is:
- A strong prescription pain medicine that contains an opioid (narcotic) that is used to treat moderate to severe around-the-clock pain.

Important information about BUTRANS:
- Get emergency help right away if you take too much BUTRANS (overdose). BUTRANS overdose can cause life-threatening breathing problems that can lead to death.
- Never give anyone else your BUTRANS. They could die from taking it. Store BUTRANS away from children and in a safe place to prevent stealing or abuse. Selling or giving away BUTRANS is against the law.

Do not use BUTRANS if you have:
- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before applying BUTRANS, tell your healthcare provider if you have a history of:
- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- heart rhythm problems (Long QT syndrome)
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you:
- have a fever.
- **are pregnant or planning to become pregnant.** BUTRANS may harm your unborn baby.
- **are breastfeeding.** BUTRANS passes into breast milk and may harm your baby.
- are taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

While using BUTRANS:
- Do not change your dose. Apply BUTRANS exactly as prescribed by your healthcare provider.
- See the detailed Instructions for Use for information about how to apply and dispose of the BUTRANS patch.
- Do not apply a BUTRANS patch if the pouch seal is broken, or the patch is cut, damaged, or changed in any way.
- Do not apply more than 1 patch at the same time unless your healthcare provider tells you to.
- You should wear 1 BUTRANS patch continuously for 7 days.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop using BUTRANS without talking to your healthcare provider.**

While using BUTRANS Do Not:
- Take hot baths or sunbathe, use hot tubs, saunas, heating pads, electric blankets, heated waterbeds, or tanning lamps. These can cause an overdose that can lead to death.
- Drive or operate heavy machinery, until you know how BUTRANS affects you. BUTRANS can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

The possible side effects of BUTRANS are:
- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, itching, redness or rash where the patch is applied. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:
- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, or you are feeling faint.

These are not all the possible side effects of BUTRANS. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Distributed by: Purdue Pharma L.P., Stamford, CT 06901-3431, **www.purduepharma.com or call 1-888-726-7535**

This Medication Guide has been approved by the U.S. Food and Drug Administration.
Issue: June 2012

Butrans® CIII
(buprenorphi I System

Instructions for Use

Butrans™ (BYOO-trans) CIII
(buprenorphine)
Transdermal System

Be sure that you read, understand, and follow these Instructions for Use before you use Butrans. Talk to your doctor or pharmacist if you have any questions.

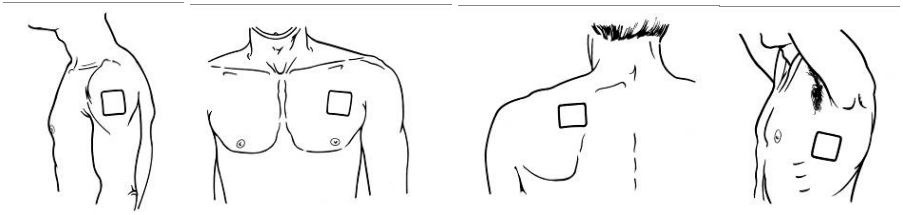
Before Applying Butrans:

- Do not use soap, alcohol, lotions, oils, or other products to remove any leftover medicine gel from a patch because this may cause more Butrans to pass through the skin.
- Each patch is sealed in its own protective pouch. Do not remove a patch from the pouch until you are ready to use it.
- Do not use a patch if the seal on the protective pouch is broken or if the patch is cut, damaged or changed in any way.
- Butrans patches are available in 3 different strengths and patch sizes. Make sure you have the right strength patch that has been prescribed for you.

Where to apply Butrans:

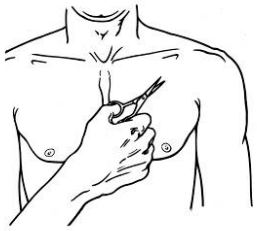
- Butrans should be applied to the **upper outer arm, upper chest, upper back, or the side of the chest** (See Figure 1). These 4 sites (located on both sides of the body) provide 8 possible Butrans application sites. You should change the skin site where you apply Butrans each week, making sure that at least 3 weeks (21 days) pass before you re-use the same skin site.

Figure 1



- Apply Butrans to **a hairless or nearly hairless skin site**. If needed, you can clip the hair at the skin site (See Figure 2). Do not shave the area. The skin site should not be irritated. **Use only water to clean** the application site. You should not use soaps, alcohol, oils, lotions, or abrasive devices. Allow the skin to dry before you apply the patch.

Figure 2



- The skin site should be free of cuts and irritation (rashes, swelling, redness, or other skin problems).

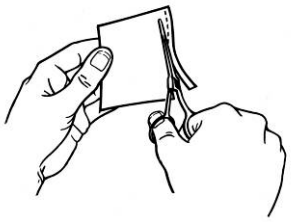
When to apply a new patch:

- When you apply a new patch, write down the date and time that the patch is applied. Use this to remember when the patch should be removed.
- Change the patch at the same time of day, one week (exactly 7 days) after you apply it.
- After removing and disposing of the patch, write down the time it was removed and how it was disposed.

How to apply Butrans:

- If you are wearing a patch, remember to remove it before applying a new one.
- Each patch is sealed in its own protective pouch.
- Use scissors to cut open the pouch along the dotted line (See Figure 3) and remove the patch. Do not remove the patch from the pouch until you are ready to use it. Do not use patches that have been cut or damaged in anyway.

Figure 3



- Hold the patch with the protective liner facing you.
- Gently bend the patch (See Figures 4a and 4b) along the faint line and slowly peel the larger portion of the liner, which covers the sticky surface of the patch.

Figure 4a

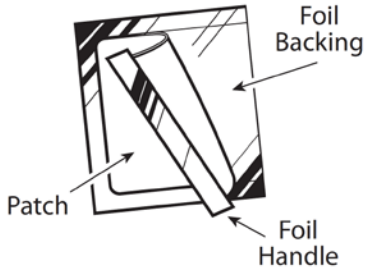
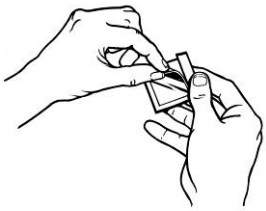
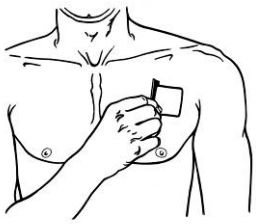


Figure 4b



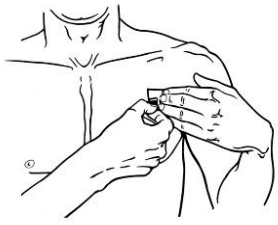
- Do not touch the sticky side of the patch with your fingers.
- Using the smaller portion of the protective liner as a handle (See Figure 5), apply the sticky side of the patch to one of the 8 body locations described above (see Where to apply Butrans?).

Figure 5



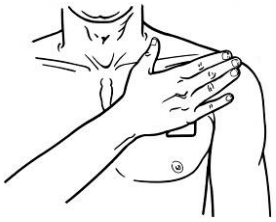
- While still holding the sticky side down, gently fold back the smaller portion of the patch. Grasp an edge of the remaining protective liner and slowly peel it off (See Figure 6).

Figure 6



- Press the entire patch firmly into place with the palm (See Figure 7) of your hand over the patch, for about 15 seconds. Do not rub the patch.

Figure 7



- Make sure that the patch firmly sticks to the skin.
- Go over the edges with your fingers to assure good contact around the patch.
- Always wash your hands after applying or handling a patch.
- After the patch is applied, write down the date and time that the patch is applied. Use this to remember when the patch should be removed.

If the patch falls off right away after applying, throw it away and put a new one on at a different skin site **(see Disposing of Butrans Patch)**.

If a patch falls off, do not touch the sticky side of the patch with your fingers. A new patch should be applied to a different site. **Patches that fall off should not be re-applied**. They must be thrown away correctly.

If the edges of the Butrans patch start to loosen:

- Apply first aid tape only to the edges of the patch.
- If problems with the patch not sticking continue, cover the patch with special see-through adhesive dressings (for example Bioclusive or Tegaderm).
    - Remove the backing from the transparent adhesive dressing and place it carefully and completely over the Butrans patch, smoothing it over the patch and your skin.
- **Never cover a Butrans patch with any other bandage or tape. It should only be covered with a special see-through adhesive dressing. Talk to your doctor or pharmacist about the kinds of dressing that should be used.**

If your patch falls off later, but before 1 week (7 days) of use, throw it away properly **(see Disposing of a Butrans Patch)** and apply a new patch at a different skin site. Be sure to let your doctor know that this has happened. Do not replace the new patch until 1 week (7 days) after you put it on (or as directed by your doctor).

Disposing of Butrans Patch:

Butrans patches must be disposed of by flushing them down the toilet or using the Patch-Disposal Unit.

To flush your Butrans patches down the toilet:
Remove your Butrans patch, fold the sticky sides of a used patch together (See Figure 8) and flush it down the toilet right away.

Figure 8

When disposing of unused Butrans patches you no longer need, remove the leftover patches from their protective pouch and remove the protective liner. Fold the patches in half with the sticky sides together, and flush the patches down the toilet.

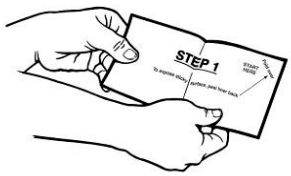
Do not flush the pouch or the protective liner down the toilet. These items can be thrown away in the trash.

If you prefer not to flush the used patch down the toilet, you must use the Patch-Disposal Unit provided to you to discard the patch.

Never put used Butrans patches in the trash without first sealing them in the Patch-Disposal Unit.

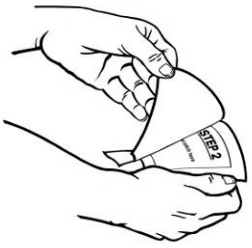
To dispose of Butrans patches in household trash using the Patch-Disposal Unit:
Remove your patch and follow the directions printed on the Patch-Disposal Unit (See Figure 9) or see complete instructions below**. Use one Patch-Disposal Unit for each patch.**

Figure 9



1. Peel back the disposal unit liner to show the sticky surface (See Figure. 10).

Figure 10

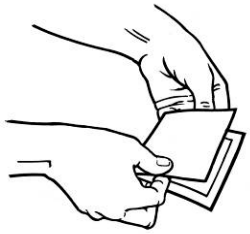


2. Place the sticky side of the used or unused patch to the indicated area on the disposal unit (See Figure 11).

Figure 11

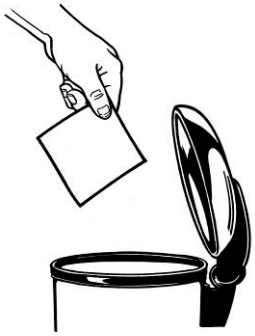
3. Close the disposal unit by folding the sticky sides together (See Figure 12). Press firmly and smoothly over the entire disposal unit so that the patch is sealed within.

Figure 12



4. The closed disposal unit, with the patch sealed inside may be thrown away in the trash (See Figure 13).

Figure 13



Do not put <u>unused</u> patches in household trash without first sealing them in the Patch-Disposal Unit.

Always remove the leftover patches from their protective pouch and remove the protective liner. The pouch and liner can be disposed of separately in the trash and should not be sealed in the Patch-Disposal Unit.

Distributed by: **Purdue Pharma L.P.**
Stamford, CT 06901-3431
Manufactured by: **LTS Lohmann Therapie-Systeme AG**
Andernach, Germany

Issued: June 2010

Bioclusive is a trademark of Systagenix Wound Management (US), Inc.
Tegaderm is a trademark of 3M.

Medication Guide

OPANA®ER (Ō-pan-a)

(oxymorphone hydrochloride extended-release) Tablets, CII

OPANA ER is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to treat moderate to severe around-the-clock pain.

Important information about OPANA ER:

- Get emergency help right away if you take too much OPANA ER (overdose). OPANA ER overdose can cause life threatening breathing problems that can lead to death.
- Never give anyone else your OPANA ER. They could die from taking it. Store OPANA ER away from children and in a safe place to prevent stealing or abuse. Selling or giving away OPANA ER is against the law.

Do not take OPANA ER if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before taking OPANA ER, tell your healthcare provider if you have a history of:

- head injury, seizures
- problems urinating
- liver, kidney, thyroid problems
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** OPANA ER may harm your unborn baby.
- **breastfeeding.** OPANA ER may pass into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

When taking OPANA ER:

- Do not change your dose. Take OPANA ER exactly as prescribed by your healthcare provider.
- Take your prescribed dose every 12 hours at the same time every day on an empty stomach, at least 1 hour before or 2 hours after meals. Do not take more than your prescribed dose in 24 hours. If you miss a dose, take the missed dose as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule.
- Swallow OPANA ER whole. Do not cut, break, chew, crush, dissolve, or inject OPANA ER.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking OPANA ER without talking to your healthcare provider.**
- After you stop taking OPANA ER, flush any unused tablets down the toilet.

While taking OPANA ER Do Not:

- Drive or operate heavy machinery, until you know how OPANA ER affects you. OPANA ER can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

The possible side effects of OPANA ER:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, or you are feeling faint.

These are not all the possible side effects of OPANA ER. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Manufactured for: Endo Pharmaceuticals Inc, Chadds Ford, PA 19317, www.endo.com or call 1-800-462-3636

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issue: July 2012

endo Pharmaceuticals

Medication Guide

MS CONTIN® (MS-KON-tin)
(morphine sulfate controlled-release) Tablets, CII

MS CONTIN is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to treat moderate to severe around-the-clock pain.

Important information about MS CONTIN:

- Get emergency help right away if you take too much MS CONTIN (overdose). MS CONTIN overdose can cause life-threatening breathing problems that can lead to death.
- Never give anyone else your MS CONTIN. They could die from taking it. Store MS CONTIN away from children and in a safe place to prevent stealing or abuse. Selling or giving away MS CONTIN is against the law.

Do not take MS CONTIN if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before taking MS CONTIN, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** MS CONTIN may harm your unborn baby.
- **breastfeeding.** MS CONTIN passes into breast milk and may harm your baby.
- taking prescription or over the counter medicines, vitamins, or herbal supplements.

When taking MS CONTIN:

- Do not change your dose. Take MS CONTIN exactly as prescribed by your healthcare provider.
- Take each dose at the same time every day. If you miss a dose, take MS CONTIN as soon as possible and then take your next dose 8 or 12 hours later as directed by your healthcare provider. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take more than 1 dose in 8 hours.
- Swallow MS CONTIN whole. Do not cut, break, chew, crush, dissolve, or inject MS CONTIN.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking MS CONTIN without talking to your healthcare provider.**
- After you stop taking MS CONTIN, flush any unused tablets down the toilet.

While taking MS CONTIN Do Not:

- Drive or operate heavy machinery, until you know how MS CONTIN affects you. MS CONTIN can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

The possible side effects of MS CONTIN are:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, or you are feeling faint.

These are not all the possible side effects of MS CONTIN. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Manufactured by: Purdue Pharma L.P., Stamford, CT 06901-3431, **www.purduepharma.com or call 1-888-726-7535**

This Medication Guide has been approved by the U.S. Food and Drug Administration.
Issue: July 2012

MS Contin® CII
(morphine sulfate
controlled-release) Tablets

Medication Guide
NUCYNTA® ER (new-SINN-tah E-R)
(tapentadol extended-release) Tablets, CII

NUCYNTA® ER is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to treat moderate to severe around-the-clock pain.

Important information about NUCYNTA® ER:

- Get emergency help right away if you take too much NUCYNTA® ER (overdose). NUCYNTA® ER overdose can cause life threatening breathing problems that can lead to death.
- Never give anyone else your NUCYNTA® ER. They could die from taking it. Store NUCYNTA® ER away from children and in a safe place to prevent stealing or abuse. Selling or giving away NUCYNTA® ER is against the law.

Do not take NUCYNTA® ER if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.
- taken a monoamine oxidase inhibitor (MAOI) medicine or have taken a MAOI medicine within the last 14 days.

Before taking NUCYNTA® ER, tell your healthcare provider if you have a history of:

- head injury, seizures
- problems urinating
- liver, kidney, thyroid problems
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** NUCYNTA® ER may harm your unborn baby.
- **breastfeeding.** NUCYNTA® ER passes into breast milk and may harm your baby.
- taking prescription over-the-counter medicines, vitamins, or herbal supplements.

When taking NUCYNTA® ER:

- Do not change your dose. Take NUCYNTA® ER exactly as prescribed by your healthcare provider.
- Take your prescribed dose every 12 hours at the same time every day. Do not take more than your prescribed dose in 24 hours. If you miss a dose take the missed dose as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule.
- Swallow NUCYNTA® ER whole with enough water to make sure that you completely swallow the tablet right away. Do not cut, break, chew, crush, dissolve, or inject NUCYNTA® ER.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking NUCYNTA® ER without talking to your healthcare provider.**
- After you stop taking NUCYNTA® ER flush any unused tablets down the toilet.

While taking NUCYNTA® ER Do Not:

- Drive or operate heavy machinery, until you know how NUCYNTA® ER affects you. NUCYNTA® ER can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

The possible side effects of NUCYNTA® ER are:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, a seizure, or you are feeling faint.
- agitation, hallucinations, coma, feeling overheated, or heavy sweating.

These are not all the possible side effects of NUCYNTA® ER. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Manufactured by: Janssen Ortho LLC, Gurabo, PR 00778; Manufactured for: Janssen Pharmaceuticals, Inc. Titusville, NJ 08560, *www.Nucynta.com* or call 1-800-526-7736

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

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