

MEDICATION GUIDE

Dexlansoprazole (DEX lan SOE pra zole) Delayed-Release Capsules, for oral use

Read this Medication Guide before you start taking dexlansoprazole delayed-release capsules and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is the most important information that I should know about dexlansoprazole delayed-release capsules?

Dexlansoprazole delayed-release capsules may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.

Dexlansoprazole delayed-release capsules can cause serious side effects, including:

- **A type of kidney problem (acute tubulointerstitial nephritis).** Some people who take proton pump inhibitor (PPI) medicines, including dexlansoprazole delayed-release capsules, may develop a kidney problem called acute tubulointerstitial nephritis, that can happen at any time during treatment with PPI medicines. Call your doctor right away if you have a decrease in the amount that you urinate or if you have blood in your urine.
- **Diarrhea.** Dexlansoprazole delayed-release capsules may increase your risk of getting severe diarrhea. This diarrhea may be caused by an infection (*Clostridium difficile*) in your intestines.
Call your doctor right away if you have watery stool, stomach pain, and fever that does not go away.
- **Bone fractures.** People who take multiple daily doses of PPI medicines for a long period of time (a year or longer) may have an increased risk of fractures of the hip, wrist or spine. You should take dexlansoprazole delayed-release capsules exactly as prescribed, at the lowest dose possible for your treatment and for the shortest time needed. Talk to your doctor about your risk of bone fracture if you take dexlansoprazole delayed-release capsules.
- **Certain types of lupus erythematosus.** Lupus erythematosus is an autoimmune disorder (the body's immune cells attack other cells or organs in the body). Some people who take PPI medicines may develop certain types of lupus erythematosus or have worsening of the lupus they already have. Call your doctor right away if you have new or worsening joint pain or a rash on your cheeks or arms that gets worse in the sun.

Dexlansoprazole delayed-release capsules can have other serious side effects. See **"What are the possible side effects of dexlansoprazole delayed-release capsules?"**.

What are dexlansoprazole delayed-release capsules?

Dexlansoprazole delayed-release capsules are a prescription medicine called a proton pump inhibitor (PPI). Dexlansoprazole delayed-release capsule reduces the amount of acid in your stomach.

Dexlansoprazole delayed-release capsules are used in people 12 years of age and older:

- for up to 8 weeks to heal acid-related damage to the lining of the esophagus (called erosive esophagitis or EE)
- for up to 6 months in adults and up to 16 weeks in children 12 to 17 years of age to continue healing of erosive esophagitis and relief of heartburn
- for 4 weeks to treat heartburn related to gastroesophageal reflux disease (GERD)

GERD happens when acid from your stomach enters the tube (esophagus) that connects your mouth to your stomach. This may cause a burning feeling in your chest or throat, sour taste or burping.

It is not known if dexlansoprazole delayed-release capsules are safe and effective in children under 12 years of age. Dexlansoprazole delayed-release capsules are not recommended in children under 2 years of age and may harm them.

Dexlansoprazole delayed-release capsules are not effective for symptoms of GERD in children under 1 year of age.

Who should not take dexlansoprazole delayed-release capsules? Do not take dexlansoprazole delayed-release capsules if you:

- are allergic to dexlansoprazole or any of the other ingredients in dexlansoprazole delayed-release capsules. See the end of this Medication Guide for a complete list of ingredients in dexlansoprazole delayed-release capsules.
- are taking a medicine that contains rilpivirine (EDURANT, COMPLERA, JULUCA) used to treat HIV-1 (Human Immunodeficiency Virus)

What should I tell my doctor before taking dexlansoprazole delayed-release capsules?

Before you take dexlansoprazole delayed-release capsules, tell your doctor about all of your medical conditions, including if you:

- have been told that you have low magnesium, calcium, potassium or sodium levels in your blood or you are taking a diuretic.
- have liver problems.
- are pregnant, think you may be pregnant or plan to become pregnant. Dexlansoprazole delayed-release capsules may harm your unborn baby. Talk to your doctor about the possible risks to an unborn baby if dexlansoprazole delayed-release capsules are taken during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if dexlansoprazole passes into your breast milk or if it will affect your baby or your breast milk. Talk to your doctor about the best way to feed your baby if you take dexlansoprazole delayed-release capsules.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

Dexlansoprazole delayed-release capsules may affect how other medicines work, and other medicines may affect how dexlansoprazole delayed-release capsules works. Especially tell your doctor if you take methotrexate (Otrexup, Rasuvo, Trexall, Reditrex, Xatmep) or digoxin. Know the medicines that you take.

How should I take dexlansoprazole delayed-release capsules?

- Take dexlansoprazole delayed-release capsules exactly as prescribed by your doctor.
- Do not change your dose or stop taking dexlansoprazole delayed-release capsules without talking to your doctor first.
- Take dexlansoprazole delayed-release capsules with or without food.
- Swallow dexlansoprazole delayed-release capsules whole. Do not chew the capsules or the pellets that are in the capsules.
- If you have trouble swallowing a whole capsule, you can open the capsule and take the contents in applesauce. See the “Instructions for Use” at the end of this Medication Guide for instructions on how to take dexlansoprazole delayed-release capsules with applesauce.
- See the “Instructions for Use” at the end of this Medication Guide for instructions on how to mix and give dexlansoprazole delayed-release capsules with water using an oral syringe or through a nasogastric tube.
- If you miss a dose of dexlansoprazole delayed-release capsules, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose. Take your next dose at your regular time. Do not take 2 doses at the same time to make up for the missed dose.
- If you take too much dexlansoprazole delayed-release capsules, call your doctor or your poison control center at 1-800-222-1222 right away or go to the nearest hospital emergency room.

What are the possible side effects of dexlansoprazole delayed-release capsules?

Dexlansoprazole delayed-release capsules may cause serious side effects, including:

- **See “What is the most important information I should know about dexlansoprazole delayed-release capsules?”.**
- **Vitamin B12 deficiency.** Dexlansoprazole delayed-release capsule reduces the amount of acid in your stomach. Stomach acid is needed to absorb Vitamin B12 properly. Talk with your doctor about the possibility of Vitamin B12 deficiency if you have been on dexlansoprazole delayed-release capsules for a long time (more than 3 years).
- **Low magnesium levels in your body can happen in people who have taken dexlansoprazole delayed-release capsules for at least 3 months.** Tell your doctor right away if you have symptoms of low magnesium levels, including seizures, dizziness, irregular heartbeat, jitteriness, muscle aches or weakness, and spasms of hands, feet or voice.
- **Stomach growths (fundic gland polyps).** People who take PPI medicines for a long time have an increased risk of developing a certain type of stomach growth called fundic gland polyps, especially after taking PPI medicines for more than 1 year.
- **Severe skin reactions.** Dexlansoprazole delayed-release capsules can cause rare but severe skin reactions that may affect any part of your body. These serious skin reactions may need to be treated in a hospital and may be life threatening:
 - Skin rash which may have blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet).
 - You may also have fever, chills, body aches, shortness of breath, or enlarged lymph nodes.Stop taking dexlansoprazole delayed-release capsules and call your doctor right away. These symptoms may be the first sign of a severe skin reaction.

The most common side effects of dexlansoprazole delayed-release capsules in adults include:

- diarrhea
- stomach pain
- nausea
- common cold
- vomiting
- gas

The most common side effects of dexlansoprazole delayed-release capsules in children 12 to 17 years of age include:

- headache
- stomach pain
- diarrhea
- pain or swelling (inflammation) in your mouth, nose or throat

Other side effects:

Serious allergic reactions. Tell your doctor if you get any of the following symptoms with dexlansoprazole delayed-release capsules:

- rash
- face swelling
- throat tightness
- difficulty breathing

Your doctor may stop dexlansoprazole delayed-release capsules if these symptoms happen.

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

These are not all the possible side effects of dextansoprazole delayed-release capsules. For more information, ask your doctor 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 dextansoprazole delayed-release capsules?

- Store dextansoprazole delayed-release capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- Bottle of 30's and 90's count come in a child-resistant package.

Keep dextansoprazole delayed-release capsules and all medicines out of the reach of children.

General information about the safe and effective use of dextansoprazole delayed-release capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use dextansoprazole delayed-release capsules for a condition for which it was not prescribed. Do not give dextansoprazole delayed-release capsules 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 dextansoprazole delayed-release capsules. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about dextansoprazole delayed-release capsules that is written for health professionals.

For more information, call Alembic Pharmaceuticals Limited at 1-866-210-9797.

What are the ingredients in dextansoprazole delayed-release capsules?

Active ingredient: dextansoprazole.

Inactive ingredients: colloidal silicon dioxide, confectioner's sugar, croscarmellose sodium, hydroxypropyl cellulose, hypromellose, magnesium carbonate, methacrylic acid copolymer dispersion, methacrylic acid and methyl methacrylate copolymer (1:1), methacrylic acid and methyl methacrylate copolymer (1:2), polyethylene glycol 8000, polysorbate 80, sodium lauryl sulfate, sugar spheres (composed of corn starch, sucrose and water), talc, titanium dioxide and triethyl citrate.

The capsule shell contains carrageenan, hypromellose and potassium chloride. Additionally, 30 mg capsule shell contains FD&C Blue No. 1, iron oxide red, iron oxide yellow, titanium dioxide and whereas 60 mg capsule shell contains iron oxide red.

The capsule shells are printed with edible ink containing black iron oxide, potassium hydroxide and shellac.

Manufactured by:

Alembic Pharmaceuticals Limited

Formulations Division IV,

Jarod 391510, Gujarat, India

Manufactured for:

Alembic Pharmaceuticals, Inc.

Bedminster, NJ 07921, USA

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

Revised: 01/2025

INSTRUCTIONS FOR USE

Dexlansoprazole (DEX lan SOE pra zole) Delayed-Release Capsules, for oral use

Taking dexlansoprazole delayed-release capsules with applesauce:

1. Place 1 tablespoon of applesauce into a clean container.
2. Carefully open the capsule and sprinkle the pellets onto the applesauce.
3. Swallow the applesauce and pellets right away. Do not chew the pellets. Do not save the applesauce and pellets for later use.

Giving dexlansoprazole delayed-release capsules with water using an oral syringe:

1. Place 20 mL of water into a clean container.
2. Carefully open the capsule and empty the pellets into the container of water.
3. Use an oral syringe to draw up the water and pellet mixture.
4. Gently swirl the oral syringe to keep the pellets from settling.
5. Place the tip of the oral syringe in your mouth. Give the medicine right away. Do not save the water and pellet mixture for later use.
6. Refill the syringe with 10 mL of water and swirl gently. Place the tip of the oral syringe in your mouth and give the medicine that is left in the syringe.
7. Repeat step 6.

Giving dexlansoprazole delayed-release capsules with water through a nasogastric tube (NG tube):

For people who have an NG tube that is **size 16 French or larger**, dexlansoprazole delayed-release capsules may be given as follows:

1. Place 20 mL of water into a clean container.
2. Carefully open the capsule and empty the pellets into the container of water.
3. Use a 60 mL catheter-tip syringe to draw up the water and pellet mixture.
4. Gently swirl the catheter-tip syringe to keep the pellets from settling.
5. Connect the catheter-tip syringe to the NG tube.
6. Give the mixture right away through the NG tube that goes into the stomach. Do not save the water and pellet mixture for later use.
7. Refill the catheter-tip syringe with 10 mL of water and swirl gently. Flush the NG tube with the water.
8. Repeat step 7.

How should I store dexlansoprazole delayed-release capsules?

- Store dexlansoprazole delayed-release capsules at room temperature between 68°F to 77°F (20°C to 25°C).

Keep dexlansoprazole delayed-release capsules and all medicines out of the reach of children.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

All other trademark names are the property of their respective owners.

Manufactured by:

Alembic Pharmaceuticals Limited

Formulations Division IV,

Jarod 391510, Gujarat, India

Manufactured for:

Alembic Pharmaceuticals, Inc.

Bedminster, NJ 07921, USA

Revised: 01/2025

20040412