

PATIENT INFORMATION

NEXIUM[®] (nex-e-um) (esomeprazole magnesium) Delayed-Release Capsules and Delayed-Release Oral Suspension

Read the Patient Information that comes with NEXIUM before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

If you have any questions about NEXIUM, ask your doctor.

WHAT IS NEXIUM?

NEXIUM is a prescription medicine called a proton pump inhibitor (PPI).

NEXIUM is used in adults:

- to treat the symptoms of gastroesophageal reflux disease (GERD). NEXIUM may also be prescribed to heal acid-related damage to the lining of the esophagus (erosive esophagitis), and to help continue this healing.

GERD is a chronic condition (lasts a long time) that occurs when acid from the stomach backs up into the esophagus (food pipe) causing symptoms, such as heartburn, or damage to the lining of the esophagus. Common symptoms include frequent heartburn that will not go away, a sour or bitter taste in the mouth, and difficulty swallowing.

- to reduce the risk of stomach ulcers in some people taking pain medicines called non-steroidal anti-inflammatory drugs (NSAIDs).
- to treat a stomach infection (*Helicobacter pylori*), along with the antibiotics amoxicillin and clarithromycin.
- for the long-term treatment of Zollinger-Ellison Syndrome. Zollinger-Ellison Syndrome is a rare condition in which the stomach produces a more than normal amount of acid.

For adolescents 12 to 17 years of age, NEXIUM may be prescribed for short-term treatment of GERD.

NEXIUM has not been shown to be safe and effective in children under the age of 12.

WHO SHOULD NOT TAKE NEXIUM?

Do not take NEXIUM if you:

- are allergic to any of the ingredients in NEXIUM. See the end of this leaflet for a complete list of ingredients in NEXIUM.
- Are allergic to any other Proton Pump Inhibitor (PPI) medicine

WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING NEXIUM?

Tell your doctor about all your medical conditions, including if you:

- have liver problems
- are pregnant, think you may be pregnant, or are planning to become pregnant. It is not known whether taking NEXIUM during pregnancy may harm your unborn baby.
- are breastfeeding or planning to breastfeed. You should not breastfeed while taking NEXIUM. Talk with your doctor about the best way to feed your baby if you take NEXIUM.

Tell your doctor about all of the medicines you take including prescription and non-prescription drugs, vitamins and herbal supplements. NEXIUM may affect how other medicines work, and other medicines may affect how NEXIUM works. Especially tell your doctor if you take:

- warfarin (COUMADIN)
- ketoconazole (NIZORAL)
- voriconazole (VFEND)
- atazanavir (REYATAZ)
- products that contain iron
- digoxin (LANOXIN, LANOXICAPS)

HOW SHOULD I TAKE NEXIUM?

- Take NEXIUM exactly as prescribed by your doctor.
- Do not change your dose or stop NEXIUM without talking to your doctor.
- Take NEXIUM at least 1 hour before a meal.
- Swallow NEXIUM capsules whole. Never chew or crush NEXIUM.
- If you have difficulty swallowing NEXIUM capsules, you may open the capsule and empty the contents into a tablespoon of applesauce. Be sure to swallow the applesauce right away. Do not store it for later use.
- If you forget to take a dose of NEXIUM, 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 a double dose to make up for a missed dose.
- If you take too much NEXIUM, tell your doctor right away.
- See the “Patient Instructions for Use” at the end of this leaflet for instructions how to take NEXIUM Delayed-Release Oral Suspension, and how to mix and give NEXIUM Delayed-Release Capsules and NEXIUM For Delayed-Release Oral Suspension, through a nasogastric tube or gastric tube.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF NEXIUM?

The most common side effects with NEXIUM may include:

- Headache
- Diarrhea
- Nausea
- Gas
- Abdominal pain
- Constipation
- Dry mouth

Tell your doctor about any side effects that bother you or that do not go away. These are not all the possible side effects with NEXIUM. Talk with your doctor or pharmacist if you have any questions about side effects.

HOW SHOULD I STORE NEXIUM?

- Store NEXIUM at room temperature between 59°F to 86°F (15°C to 30°C).
- Keep the container of NEXIUM closed tightly.

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

GENERAL ADVICE

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

This Patient Information leaflet provides a summary of the most important information about NEXIUM. For more information, ask your doctor. You can ask your doctor or pharmacist for information that is written for healthcare professionals. For more information, go to www.purplepill.com or call toll free 1-800-463-9486.

PATIENT INSTRUCTIONS FOR USE

For instructions on taking Delayed-Release Capsules, please see “**HOW SHOULD I TAKE NEXIUM?**”

Take NEXIUM Delayed-Release Oral Suspension as follows:

- Empty the contents of a packet into a container with 1 tablespoon (15 mL) of water
- Stir.
- Leave 2 to 3 minutes to thicken.
- Stir and drink within 30 minutes.

If any medicine remains after drinking, add more water, stir, and drink right away.

NEXIUM Delayed-Release Capsules and NEXIUM for Delayed-Release Oral Suspension may be given through a nasogastric tube (NG tube) or gastric tube, as prescribed by your doctor. Follow the instructions below:

NEXIUM Delayed-Release Capsules:

- Open the capsule and empty the granules into a 60 mL (cc) catheter tipped syringe. Mix with 50 mL (cc) of water. Use only a catheter tipped syringe to give NEXIUM through a NG tube.
- Replace the plunger and shake the syringe well for 15 seconds. Hold the syringe with the tip up and check for granules in the tip.
- Do not give the granules if they have dissolved or have broken into pieces.
- Attach the syringe to the NG tube and give the medicine in the syringe through the NG tube into the stomach.
- After giving the granules, flush the NG tube with more water.

NEXIUM For Delayed-Release Oral Suspension:

- Add 15 mL of water to a catheter tipped syringe and then add the contents of a NEXIUM packet (as instructed by your doctor). Use only a catheter tipped syringe to give NEXIUM through a NG tube or gastric tube.
- Shake the syringe right away and then leave it for 2 to 3 minutes to thicken.
- Shake the syringe and give the medicine through the NG or gastric tube (French size 6 or larger) into the stomach within 30 minutes.
- Refill the syringe with 15 mL (cc) of water.
- Shake and flush any remaining contents from the NG tube or gastric tube into the stomach.

WHAT ARE THE INGREDIENTS IN NEXIUM?

Active ingredient: esomeprazole magnesium trihydrate

Inactive ingredients in NEXIUM Delayed-Release Capsules (including the capsule shells):

glyceryl monostearate 40-55, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer type C, polysorbate 80, sugar spheres, talc, triethyl citrate, gelatin, FD&C Blue #1, FD&C Red #40, D&C Red #28, titanium dioxide, shellac, ethyl alcohol, isopropyl alcohol, n-butyl alcohol, propylene glycol, sodium hydroxide, polyvinyl pyrrolidone, and D&C Yellow #10.

Inactive granules in NEXIUM Delayed-Release Oral Suspension: dextrose, xanthan gum, crospovidone, citric acid, iron oxide, and hydroxypropyl cellulose.

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Wilmington, DE 19850

Item number

December 2007