

Pr NEXIUM[®]
esomeprazole

PART III: CONSUMER INFORMATION

This leaflet is part III of a three-part "Product Monograph" published when NEXIUM was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about NEXIUM. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT NEXIUM

What the medication is used for:

In adults, NEXIUM is used for the treatment of acid-related disorders such as:

- reflux esophagitis (tissue damage caused by stomach content flowing back up the food pipe) and symptoms of gastroesophageal reflux disease (GERD) in patients with reflux esophagitis
- duodenal ulcers caused by infection with a bacterium called *Helicobacter pylori* in combination with other antibiotics, and to help reduce the risk of these ulcers from coming back
- the symptoms of nonerosive reflux disease (NERD), which are not related to tissue damage within the food pipe, such as: a burning feeling rising from the chest towards the neck (heartburn) and the flow of bitter/sour juice into the mouth (regurgitation)
- rare pathological hypersecretory conditions, including "Zollinger-Ellison syndrome", which cause the stomach to produce large amounts of acid.

NEXIUM is also used to heal and/or reduce the risk of ulcers that can be caused by medication you may be taking for pain or joint problems such as NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) or acetylsalicylic acid (i.e. Aspirin[®]).

In children (1- 17 years of age), NEXIUM is used for the treatment of acid-related disorders such as:

- reflux esophagitis (tissue damage caused by stomach content flowing back up the food pipe) and symptoms of gastroesophageal reflux disease (GERD) in patients with reflux esophagitis
- the symptoms of nonerosive reflux disease (NERD), which are not related to tissue damage within the food pipe, such as: a burning feeling rising from the chest towards the neck (heartburn) and the flow of bitter/sour juice into the mouth (regurgitation).

What it does:

NEXIUM works by causing less acid to be made in your stomach.

When it should not be used:

If you are allergic to the active ingredient esomeprazole or any of the other ingredients of NEXIUM (see What the important nonmedicinal ingredients are). If you think you may be allergic, ask your doctor for advice.

What the medicinal ingredient is:

NEXIUM contains esomeprazole magnesium trihydrate as the active ingredient.

What the important nonmedicinal ingredients are:

Each NEXIUM tablet contains the following non-medicinal ingredients (listed in alphabetical order): cellulose microcrystalline, crospovidone, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, iron oxide, magnesium stearate, methacrylic acid ethylacrylate copolymer, polyethylene glycol, polysorbate, synthetic paraffin, sodium stearyl fumarate, sugar spheres, talc, titanium dioxide, triethyl citrate.

NEXIUM granules for oral suspension contain the following non-medicinal ingredients (listed in alphabetical order): citric acid, crospovidone, dextrose, glycerol monostearate, hydroxypropyl cellulose, hypromellose, iron oxide, magnesium stearate, methacrylic acid copolymer type C, polysorbate, sugar spheres, talc, triethyl citrate, xanthan gum.

Check with your doctor or pharmacist if you think you may be allergic to any of the above ingredients.

What dosage forms it comes in:

NEXIUM 20 mg tablets come in blister packages that contain 30 tablets. NEXIUM 40 mg tablets come in blister packages that contain 30 or 60 tablets, or bottles that contain 100 tablets.

NEXIUM 10 mg granules for oral suspension come in unit dose sachets in cartons of 30.

WARNINGS AND PRECAUTIONS

BEFORE or DURING your use of NEXIUM talk to your doctor or pharmacist about:

symptoms that may be a sign of a more serious problem in your stomach or intestine such as: trouble swallowing, unplanned weight loss, vomiting blood or food, or black (blood-stained) stools

if you are pregnant or trying to become pregnant

if you are allergic to esomeprazole or any other ingredients or components of the container

if you have health problems now or have had any in the past other medications you take, including ones you can buy without a prescription.

INTERACTIONS WITH NEXIUM

Blood levels of some drugs may be influenced if NEXIUM is taken at the same time as drugs used to prevent fungal infections (itraconazole, ketoconazole, voriconazole), anxiety (diazepam), epilepsy (phenytoin) and drugs to speed up stomach emptying

(cisapride*). However, none of these interactions have been shown to change the effectiveness of NEXIUM or the other drug.

Drugs used for blood clotting (warfarin or coumarin derivatives) have been reported to interact with NEXIUM. Speak to your doctor or pharmacist if you are taking any of these drugs.

NEXIUM may decrease the effectiveness of some drugs used for HIV treatment; atazanavir and nelfinavir should not be used with NEXIUM.

During episodic dosing of NEXIUM when needed, your response to potential drug interactions may change as compared to daily dosing during the entire, initial treatment period.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines.

* no longer marketed in Canada

PROPER USE OF NEXIUM

Administration:

NEXIUM may be taken with food or on an empty stomach.

Tablets:

The tablet may be swallowed whole with water. It may also be put in half a glass of water where it will break apart. This will make it easier to swallow. Be sure to swallow all the tiny pellets that come out of the tablet without chewing them. Don't let the pellets sit in water for more than 30 minutes before drinking them. After drinking, rinse the glass with water and drink this as well.

Granules for Oral suspension:

Empty the contents of each sachet into a container containing 1 tablespoon (15 mL) of water. Stir. Leave for a few minutes to thicken. The mixture will appear as a thick yellow suspension with small white and/or brownish granules. Stir again and drink within 30 minutes. If any material remains after drinking, add more water, stir, and drink right away.

Usual dose:

Adults

Take all doses of NEXIUM as directed by your doctor. Do so even when you feel well. In some cases, daily doses are needed to control your pain and symptoms and to help damaged areas heal. The suggested dose for treating acute disease is 20 to 40 mg once a day for 2 to 8 weeks. Your doctor may suggest that you continue taking NEXIUM 20 mg each day. This is to keep your symptoms from coming back.

Follow the directions given to you by your doctor. They may differ from the information contained in this leaflet.

NEXIUM may be used together with antibiotic drugs for one week to treat ulcers caused by *Helicobacter pylori*. This also helps to reduce the risk of these ulcers from coming back. Your prescription may say NEXIUM 1-2-3 A[®]. This tells the pharmacist to give you three different drugs (NEXIUM and two antibiotics). The pharmacist should also give you information on the two antibiotics that will be used in combination with NEXIUM.

If you receive NEXIUM plus antibiotic drugs, take all three drugs twice each day. Do so at the correct time each day for one week. This will ensure they work properly. Studies have shown that patients who take their drugs as prescribed, have better ulcer healing rates and greater success getting rid of their *Helicobacter pylori* infection.

It is important to take NEXIUM until your doctor tells you to stop. This is true even if you start to feel better in a few days. NEXIUM needs to be taken for the full treatment duration to help correct acid problems.

Maintenance Treatment of NERD (on-demand) dose

After initial treatment of NERD, your doctor may suggest that you take NEXIUM 20 mg once daily, as needed, if symptoms of heartburn and regurgitation return periodically. Contact your doctor if your symptoms get worse, persist or if new symptoms arise.

Children (1 – 17 years of age)

Take all doses of NEXIUM as directed by your doctor. Do so even when you/your child feels well. NEXIUM needs to be taken for the full treatment duration to help correct acid problems.

Follow the directions given to you by your doctor. They may differ from the information contained in this leaflet.

Children (1 – 11 years of age)

The suggested dose for treating acute disease is 10 mg (1 sachet) or 20 mg (2 sachets) once daily for 8 weeks.

Children (12 – 17 years of age)

The suggested dose for treating acute disease is 20 or 40 mg once a day for 2 to 8 weeks.

How to use a compliance pack:

There are 14 days of labeled tablets, with one extra to make 15. All 15 tablets, including the one labeled "Take this tablet last", are exactly the same. Once you have finished the 14 labeled tablets in the blister pack, take the one marked "Take this tablet last" before starting your next blister pack.

To treat ulcers caused by *Helicobacter pylori* in adults, take one 20 mg tablet from each of the two blisters (2 tablets per day) that match the day you start the pack.

Overdose:

Call your doctor, pharmacist or regional poison control centre right away in case of an overdose.

Missed Dose:

If you/your child miss a dose of NEXIUM, and remember within 12 hours, take the tablet/sachet as soon as possible. Then go back to the regular schedule. If more than 12 hours have passed, do not take the missed dose. Do not double the dose. Just take the next dose on time.

SIDE EFFECTS OF NEXIUM AND WHAT TO DO ABOUT THEM

Like any drug, NEXIUM may cause side effects in some people. Side effects that may occur are usually mild. They usually go away a short time after starting NEXIUM. These side effects may not be caused by NEXIUM in your case, but only a doctor can assess this. If these become bothersome (or exceed 1-2 days), discuss with your doctor:

Common: nausea, stomach upset, diarrhea, headache

Uncommon: dry mouth, dizziness, insomnia, feeling of burning/prickliness/numbing, swelling of extremities, feeling sleepy, vertigo

Rare: taste disorders, nervousness, hair loss, increased sweating

If you experience any bothersome or unusual effects while using NEXIUM, check with your doctor or pharmacist.

SERIOUS SIDE EFFECTS OF NEXIUM, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist in all cases	Stop taking drug and call your doctor or pharmacist
feeling ill	X	
Very Rare (frequency of less than 1 in 10 000 patients)		
severe skin disorders (blisters, ulcers and/or lesions)	X	X
aggression	X	
hallucinations	X	
severely impaired liver function	X	
decreased consciousness	X	
inflammation of the kidney	X	
muscular weakness	X	
development of breasts in males	X	

⁰ These would only be seen if a blood test was taken.

HOW TO STORE NEXIUM

- Keep all tablets sealed in the blister strips and the granules for oral suspension sealed in the sachet until it is time for a dose. If you do not, moisture from the air may damage the drug.
- Keep NEXIUM well out of reach of children.
- Keep NEXIUM at room temperature (15-30°C).
- Do not keep NEXIUM in the bathroom medicine cabinet or other warm, moist places.
- Do not use NEXIUM after the expiry date marked on the pack.

SERIOUS SIDE EFFECTS OF NEXIUM, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist in all cases	Stop taking drug and call your doctor or pharmacist
Rare (frequency of greater than or equal to 1 in 10 000 patients but less than 1 in 1000 patients)		
skin reactions (such as rash, dermatitis, itching and/or hives)	X	
blurred vision	X	X
depression	X	
confusion	X	
shortness of breath	X	
inflammation in the mouth	X	
severe allergic reaction (such as swelling or anaphylactic reaction/shock)	X	X
muscle pain	X	
blood disorders (reduced number of cells in the blood, low blood sodium) ⁰	X	
inflammation of liver (skin and eyes appear yellow)	X	X
gastrointestinal fungal infection	X	
photosensitivity	X	
sore joints	X	

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program, collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By Toll-free telephone: 866-234-2345
By Toll-free fax: 866-678-6789
Online: www.healthcanada.gc.ca/medeffect
By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
Canada Vigilance National Office
Marketed Health Products Safety
and Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION ABOUT NEXIUM

NOTE: This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing, and is also available in Chinese and Punjabi.

The Consumer Information Leaflets plus the full Product Monograph, prepared for health professionals, can be found at:

www.astrazeneca.ca under Patients with Prescriptions, or by contacting the sponsor, AstraZeneca Canada Inc. at:

**Customer Inquiries – 1 (800) 668-6000,
Renseignements – 1 (800) 461-3787.**

This leaflet was prepared by AstraZeneca Canada Inc., Mississauga, Ontario L4Y 1M4.

For additional information on acid-related diseases please call the sponsor, AstraZeneca Canada Inc.

NEXIUM[®], NEXIUM 1-2-3A[®] and the AstraZeneca logo are trade-marks of the AstraZeneca group of companies.

ASPIRIN[®] is a registered trade-mark of Bayer AG, used under licence.

Last revised: December 3, 2008