

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Nexium 24HR

Esomeprazole Magnesium Delayed-Release Capsules USP

Read this carefully before you start taking NEXIUM 24HR. This leaflet is a summary and will not tell you everything about the drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about NEXIUM 24HR.

What is NEXIUM 24HR used for?

In adults, NEXIUM 24HR is used:

- To treat/relieve frequent heartburn (occurs 2 or more days a week).

Heartburn is a painful burning feeling rising from the chest to the throat. NEXIUM 24HR is not the right medicine for you if you suffer from heartburn once a week or less, or if you want immediate relief.

How does NEXIUM 24HR work?

NEXIUM 24HR works by causing less acid to be made in your stomach by blocking acid at the source. This drug may take 1 to 4 days for full effect. Make sure you take the capsules for all 14 days even if you start to feel better.

What are the ingredients in NEXIUM 24HR?

Medicinal ingredients: Esomeprazole (as esomeprazole magnesium trihydrate)
Non-medicinal ingredients: corn starch, D&C red no. 28, FD&C blue no. 1, FD&C red no. 40, gelatin, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer, pharmaceutical ink, polystyrene 80, sodium lauryl sulfate, sucrose, talc, titanium dioxide, triethyl citrate.

NEXIUM 24HR comes in the following dosage forms:
Delayed-release capsules, 30 mg (Esomeprazole (as esomeprazole magnesium trihydrate)).

What else can you do to help avoid your symptoms?

- Avoid or limit foods such as: caffeine, chocolate, spicy or fatty foods, and alcohol.
- Eat smaller, more frequent meals. Avoid eating or drinking late at night or 2-3 hours before bedtime.
- Avoid lying down or bending over soon after eating.
- Try to reduce stress.
- If you are overweight, try to reduce excess weight.
- If you smoke, try to stop smoking or reduce the amount you smoke.

Do not use NEXIUM 24HR if:

- you
- are allergic to esomeprazole, other proton pump inhibitors (e.g., pantoprazole, lansoprazole, rabeprazole or esomeprazole) or any of the other ingredients of NEXIUM 24HR.
- are taking Abacavir or ribavirin (medicines for HIV infection)
- have trouble or pain when swallowing food
- have bloody black stools or are vomiting with blood
- have chest or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness.
- have heartburn with lightheadedness, sweating or dizziness

These may be signs of a serious condition. See your doctor right away.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take NEXIUM 24HR. Talk about any health conditions or problems you may have, including if you:

- have had heartburn for over 3 months. This may be a sign of a more serious condition.
- are taking any other medicines to reduce stomach acid
- are taking other medicines for HIV (abacavir and nevirapine)
- are taking medicines for heart disease (digoxin)
- have frequent chest pain
- have frequent wheezing, particularly with heartburn
- have unexplained weight loss
- have nausea or vomiting
- have stomach pain
- have pancreas, or liver or kidney problems
- now have or in the past have had a gastric ulcer or surgery on your stomach or bowels
- are over 55 years with new or recently changed symptoms
- are pregnant, plan to become pregnant, or are breastfeeding

Other warnings you should know about:

- Tell your doctor before taking this medicine if:
- You are due to have a specific blood test (chromogranin A)
- You are due to have an endoscopy or a urea breath test

STOP USE and ask your doctor if:

- you have severe and/or persistent diarrhea
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment within a 4-month period

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with NEXIUM 24HR:

- Abacavir: Squamavir (medicines for HIV infection)
- Clobazam (a medicine to treat leg pain)
- Doxycycline (antibiotic)
- Digoxin (a heart medicine)
- Doxycycline (an emetic medicine)
- Digoxin (a heart medicine)
- Enoxacin (a medicine against cancer) or any other anticancer drug from the same class
- Ketoconazole, Itraconazole, Voriconazole (antifungal or anti-yeast medicines)
- Methotrexate (a medicine used against cancer)
- Phenytoin (an epilepsy medicine)
- Rifampin (a medicine to treat tuberculosis)
- SSRIs such as citalopram (antidepressant medicines)
- St. John's Wort (Hypericum perforatum)
- Tacrolimus (an immune system medicine)
- Warfarin (a blood-thinning medicine)
- any other prescription drug
- not marketed in Canada

How to take NEXIUM 24HR:

- 14-Day Course of Treatment
- Take 1 capsule with a glass of water, before eating in the morning.
- Do NOT chew or crush capsules. This decreases how well NEXIUM 24HR works.
- Do NOT take more than 1 capsule every 24 hours.
- Take every day for 14 days.
- Do NOT use for more than 14 days unless directed by your doctor.
- Do NOT repeat a 14-day course of treatment within a period of 4 months unless directed by your doctor.

When to Take NEXIUM 24HR Again:

You should wait at least 4 months before taking another 14-day course of treatment.

Usual dose:

Adults > 18 years of age: Take one capsule once daily for 14 days. Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

Overdose:

If you think you, or a person you are caring for, have taken too much NEXIUM 24HR, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of NEXIUM 24HR, and remember within 12 hours, take the capsule 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.

What are the possible side effects from using NEXIUM 24HR?

These are not all the possible side effects you may have when taking NEXIUM 24HR. If you experience any side effects not listed here, tell your healthcare professional. Like any drug, NEXIUM 24HR 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 24HR. These side effects may be caused by NEXIUM 24HR in your case, but only a doctor can assess this. If these become bothersome or lasted 1-2 days, discuss with your doctor.

Common: nausea, stomach upset, diarrhea, headache
Uncommon: dry mouth, dizziness, insomnia, feeling of burning/itchiness/burning, swelling of extremities, feeling sleepy, vertigo

If you experience any bothersome or unusual side effects while using NEXIUM 24HR, check with your doctor or pharmacist.

Tell your doctor right away if you have any of these symptoms:

- New or worsening joint pain
- Rash on your cheeks or arms that gets worse in the sun

Serious side effects and what to do about them			
Talk to your healthcare professional			
Symptom / effect	Only if severe	In all cases	Stop taking drug and get immediate medical help
RARE			
Skin reactions (such as rash, dermatitis, itching, and/or hives)		x	
Blurred vision		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
Muscle pain		x	
Blood disorders (reduced number of cells in the blood, low blood sodium)		x	
Inflammation of liver (skin and eyes appear yellow)			x
Gastrointestinal fungal infection		x	
Photosensitivity		x	
Sore joints		x	
Feeling ill		x	
Taste disorders		x	
Nervousness		x	
Fear loss		x	
Increased sweating		x	
VERY RARE			
Severe skin disorders (blisters, ulcers and/or lesions)			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	
Low blood magnesium (which may result in low blood calcium and/or low blood potassium)		x	
Inflammation in the gut (leading to diarrhea)		x	

If these would only be seen if a blood test was taken:

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects
You can report any unexpected side effects associated with the use of health products to Health Canada by:
• Visiting the Web page on Adverse Reaction Reporting: https://www.canada.ca/en/health-canada/services/drugs-health-products/madefact-canada.html for information on how to report online, by mail or by fax; or
• Calling toll-free at 1-866-234-2345.
NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage

Store at room temperature (15-30° C). Keep out of reach and sight of children.

If you want more information about NEXIUM 24HR:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drugpage.html>, the manufacturer's website <http://www.Nexium24.ca>, or by calling 1-800-434-1034.

This leaflet was prepared by Hukon Canada ULC.

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