

IMPORTANT: PLEASE READ

**PART III:
CONSUMER INFORMATION**

NEXIUM[®] 24HR

Esomeprazole magnesium delayed release capsules USP

Esomeprazole 20 mg (as esomeprazole magnesium trihydrate)

This leaflet is part III of a three-part "Product Monograph" published when NEXIUM 24HR 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 24HR. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT NEXIUM 24HR

What the medication is 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.

What it does:

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 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.

When it should not be used:

You should not take NEXIUM 24HR if you

- are allergic to esomeprazole, other proton pump inhibitors (e.g., pantoprazole, lansoprazole, rabeprazole or omeprazole) or any of the other ingredients of NEXIUM 24HR.
- are taking rilpivirine (medicine for HIV infection)
- are taking other medicines for HIV (atazanavir, nelfinavir, and saquinavir)
- are taking medicines for heart disease (clopidogrel)
- 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 light-headedness, sweating or dizziness

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

What the medicinal ingredient is:

NEXIUM 24HR contains esomeprazole magnesium trihydrate as the active ingredient.

What the important nonmedicinal ingredients are:

Each capsule contains (listed in alphabetical order): 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, polysorbate 80, sucrose, talc, titanium dioxide, triethyl citrate.

What dosage forms it comes in:

Capsules (delayed release) 20 mg.

WARNINGS AND PRECAUTIONS

BEFORE you use NEXIUM 24HR talk to your doctor or pharmacist 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
- have frequent chest pain
- have frequent wheezing, particularly with heartburn
- have unexplained weight loss
- have nausea or vomiting
- have stomach pain
- have jaundice or other liver 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**

Tell your doctor before taking this medicine if:

- You are due to have a specific blood test (Chromogranin A)

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

INTERACTIONS WITH NEXIUM 24HR

Drugs that may interact with NEXIUM 24HR include the following. Ask your doctor or pharmacist before use if you are taking:

- Atazanavir, Nelfinavir, Saquinavir (medicines for HIV infection)
- Cilostazol* (a medicine to treat leg pain)
- Clarithromycin (antibiotic)
- Clopidogrel (a heart medicine)
- Diazepam (an anxiety medicine)
- Digoxin (a heart medicine)
- Erlotinib (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

PROPER USE OF NEXIUM 24HR

Usual dose: Adults (18 years of age and older)

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.

Overdose:

In case of drug overdose, contact a health care practitioner, 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.

SIDE EFFECTS OF NEXIUM 24HR AND WHAT TO DO ABOUT THEM

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 not be caused by NEXIUM 24HR 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

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

This is not a complete list of side effects. For any unexpected effects while taking NEXIUM 24HR, contact your doctor or pharmacist.

SERIOUS SIDE EFFECTS OF NEXIUM 24HR, 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	
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 ⁰)	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	
Hair loss	X	
Increased sweating	X	
Very Rare (frequency of less than 1 in 10 000 patients)		
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 ⁰ (which may result in low blood calcium and/or low blood potassium)	X	
Inflammation in the gut (leading to diarrhea)	X	

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

HOW TO STORE NEXIUM 24HR

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

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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.

MORE INFORMATION ABOUT NEXIUM 24HR

NOTE: This CONSUMER INFORMATION leaflet provides you with the most current information at the time of printing.

For the most current information, the Consumer Information Leaflets plus the full Product Monograph, prepared for health professionals can be found at: <http://www.Nexium24.ca> or by contacting the sponsor, Pfizer Consumer Healthcare, a division of Pfizer Canada Inc. at: 1-888-275-9938

This leaflet was prepared by Pfizer Consumer Healthcare, a division of Pfizer Canada Inc, Mississauga, Ontario L5R 4B2

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Last Revised 21 September 2018