

PART III: CONSUMER INFORMATION

Pr PRO-CEFUROXIME - 500
Cefuroxime Axetil Tablets, USP

500 mg

This leaflet is part of PRO-CEFUROXIME - 500 Product Monograph and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PRO-CEFUROXIME - 500. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

PRO-CEFUROXIME - 500 is an antibiotic medicine. It is similar to other antibiotic medicines called cephalosporins. Your doctor has prescribed PRO-CEFUROXIME - 500 because you have an infection.

Your doctor should test the type of bacteria causing your infection and monitor whether the bacteria are sensitive to PRO-CEFUROXIME - 500 during your treatment.

Antibacterial drugs like PRO-CEFUROXIME - 500 treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, PRO-CEFUROXIME - 500 should be used exactly as directed. Misuse or overuse of PRO-CEFUROXIME - 500 could lead to the growth of bacteria that will not be killed by PRO-CEFUROXIME - 500 (resistance). This means that PRO-CEFUROXIME - 500 may not work for you in the future. Do not share your medicine.

What it does:

PRO-CEFUROXIME - 500 is used to kill the bacteria or "germs" which cause infections. The infection can be cleared up if you take your medication in the proper way.

When it should not be used:

Do not use PRO-CEFUROXIME - 500 if you are allergic to cefuroxime or to cephalosporin antibiotics or to any of the other ingredients in PRO-CEFUROXIME - 500 (see What the important nonmedicinal ingredients are).

What the medicinal ingredient is:

Cefuroxime (as cefuroxime axetil)

What the important nonmedicinal ingredients are:

In addition to cefuroxime axetil, PRO-CEFUROXIME - 500 contains the following non-medicinal ingredients: colloidal silicon dioxide, crospovidone, hydroxypropyl

cellulose, hydroxypropyl methylcellulose, magnesium stearate, polyethylene glycol and titanium dioxide.

What dosage forms it comes in:

PRO-CEFUROXIME - 500 is available as tablets for oral use in one strength, which contains 500 mg of cefuroxime (as cefuroxime axetil), supplied in package of 100.

WARNINGS AND PRECAUTIONS

BEFORE you use PRO-CEFUROXIME - 500 talk to your doctor or pharmacist if:

- you are allergic to or react badly to penicillins or other antibiotics.
- you have kidney problems, as your doctor may reduce your dose.
- you are having a urine test for sugar. False positive reactions may occur if using methods dependent on copper reduction such as Fehling's or Benedict's solution or with Clinitest Tablets. For this reason enzyme-based tests such as Tes-Tape or Clinistix should be used.
- you are pregnant or planning to become pregnant
- you are breastfeeding or planning to breastfeed. Cefuroxime is excreted in human breast milk. Discuss breastfeeding with your doctor.
- you are taking other medicines. Tell your doctor or pharmacist about all the medicines you are taking, including non-prescription drugs and natural health products

As this medication may cause dizziness, do not drive or operate machinery if you are feeling dizzy.

Talk to your doctor if the following occurs while taking PRO-CEFUROXIME - 500:

- you develop hemolytic anemia (breakdown of red blood cells) with symptoms such as pale skin, weakness, tiredness, shortness of breath, yellowing of your skin and/or the whites of your eyes.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with PRO-CEFUROXIME - 500 include:

- Medicines used to reduce the amount of acid in your stomach (e.g. antacids used to treat heartburn) can affect how PRO-CEFUROXIME - 500 works.
- Medicines that promote the production of urine (such as furosemide and ethacrynic acid) may increase the risk of kidney problems when taken while being treated with PRO-CEFUROXIME - 500.
- PRO-CEFUROXIME - 500 may reduce how well the contraceptive pill works. If you are taking the contraceptive pill while you are being treated with PRO-CEFUROXIME - 500, you also need

to use a barrier method of contraception (such as condoms). Ask your doctor for advice.

PROPER USE OF THIS MEDICATION

Note: The 250 mg cefuroxime axetil tablet is not marketed by Pro Doc Ltée.

Usual dose:

The usual length of treatment is 7 to 10 days, although your doctor may adjust the prescription to suit your treatment. During the course of treatment, all the tablets must be taken to make sure that all germs have been killed. CONTINUE TAKING THE TABLETS UNTIL THEY ARE FINISHED, EVEN IF YOU BEGIN TO FEEL BETTER.

YOU SHOULD NOT INCREASE OR DECREASE THE PRESCRIBED DOSE UNLESS ADVISED BY YOUR DOCTOR.

Take PRO-CEFUROXIME - 500 Tablets with food. This will help to make the treatment more effective.

You must take the medicine as prescribed by your doctor. If you are not sure how many tablets to take, or how often to take them, consult your doctor or pharmacist.

The usual dose for adults is one 250 mg tablet twice a day. PRO-CEFUROXIME - 500 has a bitter taste, therefore, **do not chew or crush the tablets** but swallow each one whole with a drink of water.

Overdose:

If you think you have taken too much PRO-CEFUROXIME - 500, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

It is important to follow the dosage instructions on the label of your medicine. Taking more than this dose is unlikely to be dangerous unless a large quantity of tablets is taken all at once. In this case, contact your doctor or nearest hospital emergency department immediately.

Missed Dose:

If you forget to take a dose, take another as soon as possible. Then continue with the normal dose. Do not double doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If you experience wheeziness and tightness of chest, swelling of eyelids, face or lips, or develop skin lumps or hives, or a skin rash (red spots), tell your doctor immediately. Do not take any more medicine unless

your doctor tells you to do so. Your doctor may decide to stop your treatment.

You may experience diarrhea, nausea, vomiting, loose stools, abdominal pain, headache, dizziness, diaper rash, drowsiness, inflammation of the vagina or symptoms that you do not understand. There is no need to stop taking your tablets, but you should tell your doctor of any of these symptoms as soon as possible.

If you experience symptoms such as severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness, you may have *Clostridium difficile* colitis (bowel inflammation). If this occurs, stop taking PRO-CEFUROXIME - 500 and contact your doctor immediately.

Other side effects include seizure and kidney problems. PRO-CEFUROXIME - 500 may also cause an increase in a type of white blood cell (*eosinophilia*), a decrease in the number of white blood cells (*leukopenia*), decrease in number of blood platelets (cells that help blood to clot) called thrombocytopenia or an increase in some substances (*enzymes*) produced by the liver. If you are taking a blood test, you should tell your doctor that you are taking PRO-CEFUROXIME - 500, as it may affect your result.

On rare occasions, medicines like PRO-CEFUROXIME - 500 can cause an overgrowth of yeast (*Candida*) in the body which can lead to fungal infections (such as thrush). This side effect is more likely if you take PRO-CEFUROXIME - 500 for a long time. Tell your doctor as soon as possible if you think you have a fungal infection. Your doctor may need to stop your treatment.

Very rarely, PRO-CEFUROXIME - 500 may cause severe skin reactions, such as skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) known as erythema multiforme, and widespread rash with blisters and skin peeling on much of the body surface (*toxic epidermal necrolysis*), particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*). If these severe skin reactions occur, stop taking PRO-CEFUROXIME - 500 and contact your doctor immediately.

Very rarely, PRO-CEFUROXIME - 500 may cause effects such as:

- a high temperature (*fever*)
- yellowing of the whites of the eyes or skin (*jaundice*)

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- inflammation of the liver (hepatitis) with symptoms such as abdominal pain, vomiting, nausea and jaundice, and
- a faster breakdown of red blood cells leading to a form of anemia (*hemolytic anemia*) with symptoms such as fatigue, shortness of breath and looking pale

If these symptoms occur or persist, contact your doctor.

If you feel worse or you have taken all the tablets and do not feel better **TELL YOUR DOCTOR AS SOON AS POSSIBLE.**

Serious side effects and what to do about them				
Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Rare	Overgrowth of Yeast (Candida): fungal infections (such as thrush)		√	
Rare	Bowel Inflammation : severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness			√
Very rare	Allergic Reactions: wheeziness and tightness of chest, swelling of eyelids, face or lips, or develop skin lumps or hives, or a skin rash (red spots)			√
Very rare	Skin Reactions: skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area,			√

Serious side effects and what to do about them				
Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
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	with a dark ring around the edge); widespread rash with blisters and skin peeling on much of the body surface, particularly around the mouth, nose, eyes and genitals			

This is not a complete list of side effects. For any unexpected effects while taking PRO-CEFUROXIME - 500, contact your doctor or pharmacist.

HOW TO STORE IT

Store tablets between 15°C and 30°C. Keep in tightly closed container.

Keep out of reach and sight of children.

Reporting Side Effects

You can report any suspected 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/medeffect-canada/adverse-reaction-reporting.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.

MORE INFORMATION

If you want more information about PRO-CEFUROXIME - 500:

- Talk to your healthcare professional

- Find the full Product Monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); or by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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