

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr PRO-CEPHALEXIN

Cephalexin For Oral Suspension
125 mg/5 mL and 250 mg/5 mL

Manufacturer Standard

Read this carefully before you start taking PRO-CEPHALEXIN and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about PRO-CEPHALEXIN.

What is PRO-CEPHALEXIN used for?

- PRO-CEPHALEXIN is used to treat certain bacterial infections in the:
 - respiratory tract;
 - ear (otitis media);
 - genitals and urinary tract;
 - bones and joints;
 - skin and soft tissue.
- Antibacterial drugs like PRO-CEPHALEXIN treat only bacterial infections. They do not treat viral infections, such as the common cold.

How does PRO-CEPHALEXIN work?

PRO-CEPHALEXIN is an antibiotic that:

- Stops the growth of bacteria
- Kills bacteria

What are the ingredients in PRO-CEPHALEXIN?

Medicinal ingredients: Cephalexin (cephalexin monohydrate)

Non-medicinal ingredients:

125 mg / 5 mL Oral Solution: colloidal silicon dioxide, FD & C Red #40, sodium benzoate, strawberry flavouring (maize maltodextrin, flavourings, propylene glycol), sucrose and xanthan gum.

250 mg / 5 mL Oral Solution: colloidal silicon dioxide, FD & C Red #40, sodium benzoate, strawberry flavouring (maize maltodextrin, flavourings, propylene glycol), sucrose and xanthan gum.

Do not use PRO-CEPHALEXIN if:

- you are allergic to cephalexin, cephalosporin antibiotics or to any of the other ingredients in PRO-CEPHALEXIN

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

- you are allergic to or react badly to penicillins or other antibiotics.
- you have intestinal or bowel problems.
- you have kidney problems.
- you are pregnant or plan to be pregnant.
- you are breast-feeding or plan to breast-feed.

Other warnings that you should know about:

- Using antibiotics like PRO-CEPHALEXIN may cause with Clostridium difficile-associated disease (CDAD). See “Serious side effects and what to do about them”, below.
- PRO-CEPHALEXIN may interfere with some blood and urine test results. Talk to your doctor if you are given a blood or urine test while taking PRO-CEPHALEXIN.

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

How to take PRO-CEPHALEXIN:

- Take PRO-CEPHALEXIN orally on an empty stomach.
- Although you may feel better early in treatment, PRO-CEPHALEXIN should be used exactly as directed.
- Misuse or overuse of PRO-CEPHALEXIN could lead to the growth of bacteria that will not be killed by PRO-CEPHALEXIN (resistance). This means that PRO-CEPHALEXIN may not work for you in the future.
- Do not share your medicine.

Usual dose:

Adult:

The adult dosage ranges from 1 to 4 g daily in divided doses. The usual adult dose is 1 g/day in divided doses every 6 hours.

Children:

The recommended daily dosage for children is 25 to 50 mg/kg/day in divided doses every 6 hours.

Overdose:

Symptoms of oral overdose may include:

- nausea
- vomiting
- abdominal pain
- diarrhea
- bloody urine

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

What are possible side effects from using PRO-CEPHALEXIN?

These are not all the possible side effects you may feel when taking PRO-CEPHALEXIN. If you experience any side effects not listed here, contact your healthcare professional.

You may experience diarrhea, nausea, vomiting, loose stools, abdominal pain, diaper rash, inflammation of the vagina or discharge, dizziness, fatigue, headache, agitation, confusion, hallucinations or symptoms that you do not understand. You should tell your health professional for of any of these symptoms as soon as possible.

Vertigo (loss of balance or unsteadiness), tinnitus (ringing in the ears), hearing loss and behavioural changes in young children have been reported.

PRO-CEPHALEXIN may also cause effects such as yellowing of the whites of the eyes or skin (jaundice) or the inflammation of the liver (hepatitis).

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			
Symptoms of a severe bowel condition (<i>Clostridium difficile colitis</i>): <ul style="list-style-type: none"> • persistent diarrhea • bloody or watery diarrhea • abdominal or stomach pain/cramping • blood/mucus in stool 			✓

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	
Severe skin reactions: <ul style="list-style-type: none"> • 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) • widespread rash with blisters and skin peeling on much of the body surface particularly around the mouth, nose, eyes and genitals. 			✓
Severe Cutaneous Adverse Reactions (SCAR) (severe skin reactions that may also affect other organs): <ul style="list-style-type: none"> • Skin peeling, scaling or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish) • Swelling and redness of eyes or face • Flu-like feeling, fever, chills, body aches, swollen glands, cough • Shortness of breath, chest pain or discomfort 			✓

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

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/medeffectcanada/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.

Storage:

Oral Suspension:

Store dry powder at room temperature (15°C - 30°C). Keep container tightly closed and protect from light.

The reconstituted formulation is stable for 14 days under refrigeration (2°C - 8°C). Do not freeze

If you want more information about PRO-CEPHALEXIN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); or by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or medinfo@prodoc.qc.ca.

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