

ANPRODROXIL CAPSULES/ GRANULES FOR ORAL SUSPENSION

Cefadroxil (500mg, 125mg/5ml)

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What Anprodroxil Capsules/ Granules for Oral Suspension is used for

Cefadroxil is the active ingredient for Anprodroxil Capsules/ Granules for oral suspension.

Cefadroxil can be used to treat

- Throat infections
- Urinary tract infection
- Infection in the skin

How Anprodroxil Capsules/ Granules for Oral Suspension works

Cefadroxil is an antibiotic. It belongs to a group of antibiotics that are called cephalosporins. These types of antibiotics are similar to penicillin.

Cefadroxil kills bacteria and it can be used against various sorts of infections.

Before you use Anprodroxil Capsules/ Granules for Oral Suspension

- When you must not use it

- If you have known hypersensitivity to penicillin or with known histories allergy to any of the cephalosporins or any of its ingredient.
- If you have acute porphyria (include forms of the disease

that typically affect nervous system)

- Before you start to use it

You must tell your doctor if:

- You have allergies to any medicine which you have taken previously to treat your current condition.
- You are pregnant, trying to become pregnant as the safety has not been established.
- If you are breast feeding as small quantities are found in milk of nursing mothers.
- If you experienced severe or immediate hypersensitivity reactions to a penicillin. There may be an increased risk of you being allergic to Anprodroxil Capsules/ Granules for Oral Suspension if you are allergic to penicilins.
- If you have a history of gastrointestinal disease, particularly colitis (inflammation of the colon).

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines when taken with Anprodroxil Capsules/ Granules for Oral Suspension may interfere with each other. These include:

- Aminoglycoside, medicines for infection.
- Probenecid, medicine for gout.

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking medicine.

How to use Anprodroxil Capsules/ Granules for Oral Suspension

Always take this medicine exactly as your doctor has told you. You should

check with your doctor or pharmacist if you are not sure.

- How much to use

The dose your doctor prescribes depends on the type of infection and how bad the infection is.

Patients with impaired kidney function

Your doctor might prescribe you with a lower dose if you have kidney disease.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Anprodroxil Capsules/ Granules for Oral Suspension as your doctor recommends. Do not stop taking medication, even if you feel better after a few days, unless advised by your doctor. Your infection may not clear completely if you stop taking your medicine too soon.

Directions for Reconstitution/ Mixing of Oral Suspensions

Add sufficient water (about 30ml distilled or boiled water, cooled to room temperature), close bottle and shake vigorously, and make up volume to 60ml mark with water. Shake well before each dose.

- If you forget to use it

- If you forget a dose, take it as soon as you remember it.
- However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

- If you take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this

even if there are no signs of discomfort or poisoning, you may need urgent medical attention.

Taking too many tablets may cause seizure, and other signs of central nervous system toxicity, especially in patients with kidney failure.

While you are using it

- Things you must do

Contact your doctor if your symptoms worsen or they do not improve.

Inform your doctor that you are taking Anprodroxil Capsules/ Granules for Oral Suspension if you need to perform some blood test or urine test.

If you get severe diarrhoea tell your doctor or pharmacist immediately.

- Things you must not do

Do not give Anprodroxil Capsules/ Granules for Oral Suspension to anyone else, even if their symptoms seem similar or they have same condition as you.

Your doctor has prescribed Anprodroxil Granules for Oral Suspension and Anprodroxil Capsules for you and your condition.

- Things to be careful of

- Prolonged use results in overgrowth of resistant organisms.
- Reduce the dose in patients with impaired kidney function.
- Be careful driving or operating machinery until you know how Anprodroxil Capsules/ Granules for Oral Suspension affects you.

Side effects

Like all medicines, Anprodroxil Capsules/ Granules for Oral Suspension can have side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic – hypersensitivity reaction includes skin rashes, urticaria (hives), angioedema (swelling under the skin)

and pruritus (severe itching of the skin). Anaphylaxis (severe, potentially life-threatening allergic reaction) has also been reported.

Gastrointestinal (stomach and intestinal) – nausea, vomiting and diarrhoea, abdominal discomfort

Hematologic (blood) – rises in serum aminotransferases. Eosinophilia (an abnormally high number of eosinophils, disease-fighting white blood cell in the blood) and neutropenia (an abnormally low level of neutrophils in the blood, a type of white blood cell that defends the body against bacterial and fungal infections) have occurred in patients.

Kidney – nephrotoxicity (common kidney problems that occurs when the body is exposed to a drug or toxin that causes damage to the kidneys) occurs but reversible.

Others – superinfection (an additional infection that happens during or immediately after an existing infection) with resistant microorganisms particularly *Candida* may follow treatment.

Pseudomembranous colitis (inflammation of the colon) has been reported.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Consult your doctor or pharmacist if you are in doubt or for any further information.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting)

Storage and Disposal of Anprodroxil Capsules/ Granules for Oral Suspension

- Storage

Do not use after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Capsule

The capsules should be stored below 25°C. Protect from light, moisture and heat.

Granules for Oral Suspension

Prior to reconstitution – store in a cool, dry place (15-25°C). Avoid moisture and heat.

After reconstitution – suspension must be refrigerated (2-8°C) and use within 5 days.

Keep out of the reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

Anprodroxil Capsules 500mg

- What it looks like

A white powder filled in size no. 0 capsules with maroon cap and white body.

- Ingredients

- Active ingredient
Each capsule contains Cefadroxil (base) 500mg. The source of gelatin for empty capsules is of bovine origin.
- Inactive ingredients
Other ingredients include dried corn starch, magnesium stearate and colloidal silicone dioxide.

Anprodroxil Granules for Oral Suspension 125mg/5ml

- What it looks like

Red granules with raspberry and strawberry flavour and sweet taste.

They are supplied in 60ml plastic bottle.

- Ingredients

- Active ingredient
5ml of reconstituted suspension contains Cefadroxil (base) 125mg.
- Inactive ingredients
Other ingredients includes sucrose suspension grade, microcrystalline cellulose pH101, xanthan gum, strawberry flavour (powder), raspberry powder, vanilla powder, sodium lauryl sulphate, colloidal silicone dioxide, cochineal red A and emulsion silicone 30%.

- MAL Number(s):

Anprodroxil Capsules 500mg:
MAL19992592AZ

Anprodroxil Granules for Oral
Suspension 125mg/5ml:
MAL19992591AZ

**Manufacturer and Product
Registration Holder**

Malaysian Pharmaceutical Industries
Sdn. Bhd.
Plot 14, Lebuhraya Kampung Jawa,
11900 Bayan Lepas, Penang, Malaysia.

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