

CEPHALEXIN CAPSULES/ TABLETS/ GRANULES FOR ORAL SUSPENSION

Cephalexin Monohydrate (250mg, 500mg, 125mg/5ml, 250mg/5ml)

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What Cephalexin is used for

Cephalexin monohydrate is the active ingredient for Cephalexin. It is indicated for the treatment of infections of the respiratory tract, skin and soft tissues. It is also used for the treatment of ear, nose and throat, gastrointestinal (GIT) and obstetrics and gynaecology (O&G) infections, gonorrhoea and syphilis (venereal disease).

How Cephalexin works

Cephalexin is an antibiotic that belongs to the group of medicines called cephalosporin. These medicines work by killing or stopping the growth of the bacteria, which cause infections.

Before you use Cephalexin

- 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.

- 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.
- You are breast feeding as small quantities are found in milk of nursing mothers.
- You experienced severe or immediate hypersensitivity reactions to a penicillin.
- You have kidney problem.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any of these medicine:

- Aminoglycoside, antibiotics that are used to treat certain bacterial infections.
- Probenecid, medicines used to treat chronic gout and gouty arthritis. It delays urinary excretion of cephalosporins.
- Oestrogen-containing oral contraceptives (birth control pill).

Always inform your doctor and pharmacist if you are taking any other medicines, including herbal tonics, supplements and medicines that you buy without prescription.

How to use Cephalexin

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

Adults: 250 to 500mg every 6 hours for moderate infections; in severe or deep-seated infections, the dose can be increased to 3 to 6g daily.

Children 6-12 years: 250mg every 8 hours.

Infants and children below 6 years: usual dose is 25-60mg per kg body weight per day. For severe or deep-seated infections, this should be increased to 100mg per kg body weight per day (maximum 4g/day).

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.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Cephalexin for as long 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.

- 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 use too much (overdose)

Contact your doctor immediately or go to 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.

Symptoms: Convulsions and other signs of central nervous system (CNS) toxicity have been associated with high doses, especially in patients with kidney failure.

While you are using it

- Things you must do

Inform your doctor that you are taking Cephalexin if you need to perform blood or urine test as it might affect your result.

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

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

- Things you must not do

Do not give Cephalexin to anyone else, even if their symptoms seem similar or they have same condition as you. Your doctor has prescribed Cephalexin 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 Cephalexin affects you.

Side effects

Like all medicines, Cephalexin can have side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic – hypersensitivity reaction includes skin rashes.

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 (damage to the kidney due to body exposed to a drug or toxin) occurs but reversible.

Others – superinfection (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 Cephalexin

- Storage

Do not use after the expiry date stated on the pack. The expiry

date refers to the last day of that month.

Granules for Oral Suspension

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

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

Capsule & Tablet

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

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

Cephalexin Capsules 250mg

- What it looks like

A white to near white powder filled in size no. 2 capsules with green cap and white body with 'MPI'/'UMED' marking.

- Ingredients

- Active ingredient
Each capsule contains Cephalexin monohydrate equivalent to Cephalexin base 250mg
- Inactive ingredients
Other ingredients include lactose, magnesium stearate and colloidal silicone dioxide.

Cephalexin Tablets 500mg

- What it looks like
A fawn, oblong, scored of 17x6.5mm tablet 'Life' marking a characteristic colour.

- Ingredients

- Active ingredient
Each tablet contains Cephalexin monohydrate equivalent to Cephalexin base 500mg
- Inactive ingredients
Other ingredients includes corn starch, magnesium stearate, sodium starch glycolate, povidone k-90 and isopropyl alcohol

Cephalexin Granules for Oral Suspension 125mg/5ml

- What it looks like
Cherry red granules with cherry flavour with sweet taste.

They are supplied in 60ml plastic bottle.

- Ingredients

- Active ingredient
5ml of reconstituted suspension contains Cephalexin monohydrate equivalent to Cephalexin base 125mg.
- Inactive ingredients
Other ingredients include sucrose suspension grade, methyl cellulose, sodium lauryl sulphate, cherry essence, allura red ac and emulsion silicone 30%.

Cephalexin Granules for Oral Suspension 250mg/5ml

- What it looks like
Yellow granules with banana flavour and sweet taste.

They are supplied in 60ml plastic bottle.

- Ingredients

- Active ingredient

5ml of reconstituted suspension contains Cephalexin monohydrate equivalent to Cephalexin base 250mg.

- Inactive ingredients

Other ingredients includes sucrose suspension grade, carboxymethyl cellulose sodium, sodium chloride, colloidal silicone dioxide, quinoline yellow, emulsion silicone 30%, banana flavour, vanillin and alcohol 95%.

- MAL number(s):

Cephalexin Capsules 250mg
MAL19910003A

Cephalexin Tablets 500mg
MAL19985184A

Cephalexin Granules for Oral Suspension 125mg/5ml
MAL19900375A

Cephalexin Granules for Oral Suspension 250mg/5ml
MAL19984399A

Manufacturer and Product Registration Holder

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