Package leaflet: Information for the user

Cefalexin Tablets 250 mg
Cefalexin Tablets 500 mg

Cefalexin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. **What Cefalexin is and what it is used for**
2. **What you need to know before you take Cefalexin**
3. **How to take Cefalexin**
4. **Possible side effects**
5. **How to store Cefalexin**
6. **Contents of the pack and other information**

1 What Cefalexin is and what it is used for

Cefalexin contains the active ingredient cefalexin monohydrate, which is an antibiotic.

Cefalexin is used to treat the following infections caused by bacteria that can be killed by cefalexin:

- Respiratory tract (lung and airways) infections e.g. tonsillitis, pharyngitis and bronchitis
- Middle ear infection (otitis media)
- Skin and soft tissue (e.g. muscle) infections
- Bone and joint infections
- Infections of the reproductive organs and urinary tract (e.g. cystitis), including acute inflammation of the prostate (prostatitis)
- Dental infections.

2 What you need to know before you take Cefalexin

Do not take Cefalexin:

- If you are allergic to cefalexin, other cephalosporins (similar antibiotics) or any of the other ingredients of this medicine (listed in Section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cefalexin if you:

- have had an allergic reaction to cefalexin, cephalosporins, penicillins, or other drugs in the past
- develop severe or prolonged diarrhoea during or after taking cefalexin
- have a severe kidney disorder (you may need a reduced dose)
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking cefalexin or other antibacterials.

Tell your doctor if you are having blood or urine tests. Cefalexin may interfere with these tests.

Acute generalised exanthematous pustulosis (AGEP) has been reported with the use of cefalexin. AGEP appears at the initiation of treatment as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common location: mainly localized on the skin folds, trunk, and upper extremities. The highest risk for occurre**n**ce of this serious skin reaction is within the first week of treatment. If you develop a serious rash or another of these skin symptoms, stop taking cefalexin and contact your doctor or seek medical attention immediately.

Other medicines and Cefalexin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is especially important of the following, as they may interact with your Cefalexin:

- Any other antibiotics (e.g. gentamicin, tobramycin, cefuroxime)
- Potent diuretics e.g. furosemide (water tablets used to treat high blood pressure or water retention)
- Probenecid (a treatment for gout)
- Metformin (a treatment for diabetes)
- Drugs used to treat leukaemia.

It may still be all right for you to be given Cefalexin and your doctor will be able to decide what is suitable for you.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Cefalexin should not affect your ability to drive or use machines.

Cefalexin Tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3 How to take Cefalexin

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

Adults and the elderly

The usual total daily dose is 1-4 g orally, in divided doses.

- Most infections can be treated by 500 mg every 8 hours. For skin and soft tissue infections, sore throat (streptococcal pharyngitis), and mild, uncomplicated urinary tract infections, the usual dose is 250 mg every 6 hours, or 500 mg every 12 hours.
- For more severe infections, larger doses may be needed. A reduced dose is needed for patients with severe kidney disorders.

Use in children

The usual total daily dose for children is 25-50 mg/kg (body weight) in divided doses.

- For skin and soft tissue infections, streptococcal pharyngitis, and mild, uncomplicated urinary tract infections, the total daily dose may be divided and administered every 12 hours.

For most infections the following schedule is suggested:

Children under 5 years: 125 mg every 8 hours.

Children 5 years and over: 250 mg every 8 hours.

In severe infections, the dose may be doubled. In the treatment of middle ear infections, a total daily dose of 75 to 100 mg/kg in 4 doses is required.

For oral use. The score line on the 500 mg Tablet is only there to help you break the tablet if you have difficulty swallowing it whole.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

Serious side effects

The following side effects are serious. You should stop taking this medicine and contact your doctor immediately if you experience them:

- **Serious peeling or blistering of the skin**
- **Severe diarrhoea**
- **A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).**
  See also section 2.

The following side effects have been reported

- Diarrhoea
- Feeling sick (nausea)
- Vomiting
- Indigestion
- Stomach pains
- Measles-like rash, (alone)
- Itching
- Red wheals on the skin (urticaria) (alone)
- Rash with wide spread joint pain and / or stiffness, swollen lymph glands, fever and, possibly, cloudy urine
- Changes in blood counts, which may show up as bruising or a very tired feeling. You will need a blood test to confirm this.
- Damage to your liver or kidneys which can only be detected by a blood and / or urine test
- Jaundice (yellow skin and eyes)
- Weakness
- Fainting
- Abnormally excitable behaviour
- Agitation
- Tiredness
- Headache
- Confusion
- Dizziness
- Seeing or hearing things (hallucinations)
- Encephalopathy (non-inflammatory brain disease)
- Convulsions
- Myoclonus (muscle-twitching)
- Itching of the vagina or anus caused by thrush (candidiasis).

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Cefalexin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Keep containers tightly closed.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Cefalexin contains

The active substance is cefalexin monohydrate.

The other ingredients are:

Sodium starch glycollate, magnesium stearate, povidone, methylhydroxypropylcellulose, glycerol, talc, titanium dioxide (E171), iron oxide yellow (E172) and iron oxide red (E172).

What Cefalexin looks like and contents of the pack

250 mg Tablets: Peach coloured tablet, 8.5 mm diameter and marked 'GP3'. Available in blister strips of 28 tablets.

500 mg Tablets: Peach coloured pillow-shaped tablet, 16 mm long, scored and marked 'GP4'. Available in plastic bottles of 20, 100 and 500 tablets or blisters of 3, 4, 21 or 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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