



PACKAGE LEAFLET:
INFORMATION FOR
THE USER

**Cefalexin
Capsules 250mg
Cefalexin
Capsules 500mg
(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 Capsules are and what they are used for
2. What you need to know before you take Cefalexin Capsules
3. How to take Cefalexin Capsules
4. Possible side effects
5. How to store Cefalexin Capsules
6. Contents of the pack and other information

1. WHAT CEFALEXIN CAPSULES ARE AND WHAT THEY ARE USED FOR

Cefalexin Capsules contain cefalexin as the active ingredient, which belongs to a class of antibiotics called 'cephalosporins'. Cefalexin Capsules are used to treat following infections caused by bacteria that can be killed by cefalexin:

- Respiratory tract (lung and airways) e.g. tonsillitis, pharyngitis and bronchitis
- Middle ear infections (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 gland (prostatitis)
- Dental infections.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CEFALEXIN CAPSULES

Do not take Cefalexin Capsules if you:

- Are allergic (hypersensitive) to cefalexin, other cephalosporins (similar antibiotics) or penicillin group of antibiotics, or to any of the ingredients in the product (see Section 6 and end of section 2). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- Have porphyria; a hereditary metabolic disorder.

Tell your doctor before taking Cefalexin:

- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking cefalexin or other antibacterials.

Warnings and precautions

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

- Have had allergic reaction to cefalexin, cephalosporins, penicillins or other drugs in the past
- Have a severe kidney disorder (you may need reduced dose)
- Develop diarrhoea. This could be symptom of the inflammation of the large intestine.

Other symptoms include pain and fever.

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

Take special care with Cefalexin:

Acute generalised exanthematous (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 localised on the skin folds, trunk, and upper extremities. The highest risk of occurrence of this serious skin reaction is within the first week of treatment. If you develop a serious skin rash or another of these skin symptoms, stop taking cefalexin and contact your doctor or seek medical attention immediately.

Other medicines and Cefalexin Capsules

Please tell your doctor or pharmacist if you are taking or have recently taken, or might take any other medicines. This includes medicines you buy without a prescription. In particular, tell your doctor if you are taking any of the following:

- other antibiotics, especially amphotericin, capreomycin, vancomycin, gentamicin or neomycin
- diuretics (water tablets) such as furosemide, bumetanide
- probenecid for a treatment of gout
- metformin for treatment of diabetes
- drugs used to treat leukemia

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

Cefalexin Capsules with food and drink

These capsules may be taken before, during or after your meals.

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 Capsules are not expected to affect your ability to drive or operate machinery.

Cefalexin Capsules contains Lactose

Lactose - If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

3. HOW TO TAKE CEFALEXIN CAPSULES

The doctor will decide on the most appropriate dose for you, based on the nature and severity of your infection. Always take Cefalexin Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the Capsules whole with water.

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.

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

Use all the capsules your doctor has given you. **Do not stop taking them**, even if you feel better

If you take more Cefalexin Capsules than you should

Contact your doctor or nearest hospital casualty department immediately for advice if you or a child have swallowed too many capsules. Take this leaflet, the pack or any capsules with you, if you can. Symptoms of overdose include nausea, vomiting, stomach upset, appearance of blood in the urine.

If you forget to take Cefalexin Capsules

If you miss a dose, take it as soon as you remember. If it is almost time to take the next dose, skip the missed dose and carry on as before. Do not take a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cefalexin Capsules can cause side effects, although not everyone 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).

These are the signs of an **allergic reaction**. **Stop taking the capsules immediately.**

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

The following side effects have been reported

- Diarrhoea, stomach pain, heartburn, indigestion
- Feeling sick (nausea) or being sick (vomiting)
- Measle like rash
- Itching
- Red wheals on the skin (urticaria)
- 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 be detected by a blood and/ or urine test
- Yellow skin and eye whites (jaundice)
- Abnormally excitable behaviour
- Weakness, fainting
- Feeling confused or agitated, seeing or hearing things that are not there (hallucinations), extreme restlessness
- Dizziness, tiredness, headache, sleep disorders, nervousness
- Itching around the anus or genitals (pruritus), inflamed vagina (vaginitis), discharge from the vagina caused by thrush (candidiasis or moniliasis)

Frequency not known:

A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using cefalexin if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 CAPSULES

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

Do not store above 25°C.

Store Cefalexin Capsules in their original package and keep containers tightly closed.

Do not use the capsules after the expiry 'EXP' date which is printed on the carton (the expiry date refers to the last day of the month stated).

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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Cefalexin Capsules contain

The active ingredient is cefalexin, 250mg or 500mg.

The other ingredients are lactose, magnesium stearate. The capsule shell contains black iron oxide (E172), titanium dioxide (E171), erythrosin (E127), quinoline yellow (E104) and gelatin.

What Cefalexin Capsules look like and contents of the pack

Cefalexin Capsules are grey/orange capsule containing white powder and printed with 'CHX 250' (250mg) or 'CHX 500' (500mg). They are available in blisters pack of 7, 14, 20, 21, 28, 30, 50, 56, 60, 100, or 500 capsules (not all pack sizes may be marketed).

Marketing Authorisation Holder

Marketing Authorisation Holder:
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This leaflet was last revised in 02/2019.