

Cefalexin Capsules - 250 /500 mg - S/L- Eng - PIL

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Cefalexin Capsules 250 mg Cefalexin Capsules 500 mg (cefalexin monohydrate)

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, 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'. The capsules are used to treat a variety of bacterial infections. These include:

- 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 CAPSULES

Do not take Cefalexin Capsules if you have:

- an allergy (hypersensitivity) to the cephalosporin or penicillin group of antibiotics, or to any of the ingredients in the product (see Section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- porphyria; a hereditary metabolic disorder.

Warnings and precautions

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

- kidney problems
- inflammation of the large intestine, symptoms include: diarrhoea, pain and fever
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking cefalexin or other antibacterials.

You should be aware that Cefalexin Capsules may give a false result for:

- certain blood tests
- tests for glucose in the urine

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 occurrence 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 Capsules

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor if you are taking any of the following:

- other antibiotics, especially amphotericin, capreomycin, vancomycin, or an aminoglycoside - a broad spectrum antibiotic (for example, gentamicin, tobramycin, cefuroxime or neomycin)
- diuretics (water tablets used to treat high blood pressure or water retention) such as furosemide, bumetanide
- Probenecid for gout.
- Metformin (a treatment for diabetes)
- Drugs used to treat leukaemia

Cefalexin Capsules with food and drink

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

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine if you are pregnant or planning to become pregnant. Cefalexin passes into breast milk, so tell your doctor if you are breast-feeding.

Driving and using machines

Cefalexin Capsules should not affect your ability to drive or operate machinery.

Cefalexin Capsules contains 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

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

The doctor will decide on the most appropriate dose for you, based on the nature and severity of your infection. The label will tell you how many capsules you need to take as well as how often to take them.

The recommended dose is:

Adults: The usual dose is 500 mg every 8 hours, although your doctor may tell you to take 1g to 4g a day, split up into smaller doses.

Elderly: You should take the normal adult dose, unless you have severe kidney problems, when the maximum daily dose will be 500 mg.

Use in children

Your doctor will calculate the correct dose, depending on the child's weight.

The usual total daily dose is 25mg to 50mg for each kilogram of their weight.

- 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.

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.

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 product, 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).

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 widespread 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, 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/yellow-card 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 OUT OF 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. FURTHER INFORMATION

What Cefalexin Capsules contain

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

The other ingredients are lactose, magnesium stearate. The capsule shell contains black iron oxide (E172), titanium dioxide (E171), Yellow Iron Oxide (E172) and Red Iron Oxide (E172) and gelatine.

What Cefalexin Capsules look like and contents of the pack

Cefalexin Capsules are grey/orange capsule containing white powder and printed with 'CHX 250' (250 mg) or 'CHX 500' (500 mg).

They are available in tubular containers with a temper-evident tear strip or in blister pack of 7, 14, 20, 21, 28, 30, 50, 56, 60, 100 or 500 capsules (not all pack sizes may be marketed).

To listen to or request a copy of this leaflet in Braille, large print or audio please call, 01293 827819 (UK only) Please be ready to give the following information:

Product name

Cefalexin 250 mg Capsules

Reference number

PL 49565/0023

Product name

Cefalexin 500 mg Capsules

Reference number

PL 49565/0024

Code No. : HP/DRUGS/09 /301

MA Holder:
Rudipham Limited
Unit 6, Salbrook Road Industrial Estate
Salbrook Road, Redhill, Surrey RH1 5GJ, UK

Manufacturer:
Rudipham Limited
Oak House, Reeds Crescent
Watford, WD24 4QP, UK

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