

PACKAGE LEAFLET: INFORMATION FOR THE USER

CEFALEKSIN

500mg CAPSULES

CEFALEXIN MONOHYDRATE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Cefaleksin capsules are and what they are used for
2. Before you take Cefaleksin capsules
3. How to take Cefaleksin capsules
4. Possible side effects
5. How to store Cefaleksin capsules

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

Cefaleksin 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 infections of the airways from nose to lungs, ear, bones and joints, skin and urinary or reproduction systems, including inflammation of the prostate gland. They are also used to treat dental infections.

2. BEFORE YOU TAKE CEFALEKSIN CAPSULES

Do not take Cefaleksin capsules if you have:

- an allergy (hypersensitivity) to the cephalosporin group of antibiotics, or to any of the ingredients in the product.
- porphyria; a hereditary metabolic disorder.

Take special care with Cefaleksin capsules if you have:

- an allergy to the penicillin group of antibiotics
- kidney problems inflammation of the large intestine, symptoms include: diarrhoea, pain and fever.

You should be aware that Cefaleksin capsules may give a false result for:

- certain blood tests (e.g. Coombs' test)
- glucose urine test

Taking other medicines

Please inform your doctor if you are taking or have recently taken any other medicines, including those 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 or neomycin)
- diuretics (water tablets) such as furosemide, bumetanide or probenecid for gout.
- medication for leukaemia

Taking Cefaleksin 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

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

Important information about some of the ingredients of Cefaleksin capsules

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE CEFALEKSIN CAPSULES

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.

Swallow the Capsules whole with water.

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

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

Children over 5 years: Your doctor will calculate the correct dose, depending on the child's weight. The usual daily dose is 25mg to 50mg for each kilogram of their weight and is usually split up into smaller amounts taken every 8 or 12 hours. If your child is taking Cefaleksin capsules for ear infections, he or she may have to take 75mg to 100mg for each kilogram of their weight, split up into smaller doses throughout the day.

This medicine is not recommended for use in children under 5 years of age.

If you take more Cefaleksin capsules than you should

Contact your doctor or nearest hospital casualty department IMMEDIATELY for advice if you (or someone else) have swallowed too many capsules. Take this leaflet, any remaining capsules and the pack they were in with you to the hospital.

If you forget to take Cefaleksin 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 stop taking your medicine

Keep taking this medicine until your doctor tells you to stop. DO NOT stop taking it just because you feel better. If you stop taking this medicine, your infection may return or get worse.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cefaleksin capsules can cause side effects, although not everyone gets them.

STOP taking your medicine immediately and contact your doctor if you experience:

- rash, fever, itchy skin, swelling of the lips, eyes, tongue or difficulty breathing. These are signs of an allergic reaction. Stop taking the capsules immediately
- severe skin rash with flushing, fever, blisters or ulcers in your nose or mouth, or redness, peeling and swelling of the skin
- blood disorders (if you bruise more easily, have a sore throat, fever or a chill) severe diarrhoea containing blood or mucus. Colitis (inflammation of the colon) can also occur during or after treatment
- liver damage, e.g. jaundice (yellowing of the skin and whites of eyes), hepatitis (swelling and inflammation of the liver)
- nephritis (inflamed kidneys)

Tell your doctor if you suffer from any of the following for more than a few days:

- feeling or being sick, heartburn, stomach pain, diarrhoea skin rashes
- dizziness, tiredness, headache, sleep disorders, nervousness feeling confused or agitated, hallucinations, extreme restlessness painful or swollen joints, extreme muscle tension
- itching around the anus or genitals, inflamed vagina, discharge from the vagina

Laboratory Values

Slight elevations in some laboratory blood tests of liver function have been observed.

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

5. HOW TO STORE CEFALEKSIN CAPSULES

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not store above 25 °C.

Store Cefaleksin 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.

This leaflet was last reviewed in July 2012