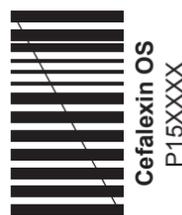


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PACKAGE LEAFLET: INFORMATION FOR THE USER

Cefalexin 125mg/5ml Powder for Oral Suspension Cefalexin 250mg/5ml Powder for Oral Suspension

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

1. WHAT CEFALEXIN ORAL SUSPENSION IS AND WHAT IT IS USED FOR

Cefalexin Oral Suspension contain cefalexin as the active ingredient, which belongs to a class of antibiotics called 'cephalosporins'.

Cefalexin Oral Suspension is 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 ORAL SUSPENSION

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.

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 antibacterial.

Warnings and precautions

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

- Have had 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 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 and urine tests. Cefalexin Oral Suspension may interfere with these tests.

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 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 Oral Suspension

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines you buy without a prescription.

This is especially important of the following, as they may interact with your Cefalexin Oral Suspension:

- 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 Oral Suspension 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 Oral Suspension should not affect your ability to drive or use machines.

Cefalexin contains sodium:

This medicine contains 6.50mg sodium (main component of cooking/table salt) in each 5ml of suspension. This is equivalent to 0.33% of the recommended maximum daily dietary intake of sodium for an adult.

Cefalexin contains Sorbitol:

Cefalexin 125mg/5ml Powder for Oral Suspension

This medicine contains 847.240 mg sorbitol in each 5ml of suspension.

Cefalexin 250mg/5ml Powder for Oral Suspension

This medicine contains 888.490 mg sorbitol in each 5ml of suspension.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Cefalexin contains sodium benzoate:

This medicine contains 4.82 mg sodium benzoate in each 5 ml cefalexin oral suspension. Sodium Benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. HOW TO TAKE CEFALEXIN ORAL SUSPENSION

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

Your pharmacist should make up the suspension before you are given it.

The bottle is turned upside down and tapped to loosen the powder.

Cefalexin 125mg/5mL oral solution: The suspension is prepared by adding 89mL of potable water and shaken until powder is dissolved.

Cefalexin 250mg/5mL oral solution: The suspension is prepared by adding 87mL of potable water and shaken until powder is dissolved.

The reconstituted solution may be further diluted with sorbitol solution BP, syrup BP or purified water if required.

Dosage

Adults and the elderly

The recommended 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 500mg every 12 hours.
- For more severe infections, larger doses may be needed. A reduced dose is needed for patients with severe kidney disorders.

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Use in children

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

- For skin and soft tissue infections, sore throat, 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 100mg/kg in 4 doses is required.

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

If you take more Cefalexin Oral Suspension than you should

Contact your doctor or nearest hospital casualty department if you or a child have swallowed too much medicine. Take this leaflet and any remaining suspension with you, if possible.

Symptoms of overdose include nausea, vomiting, stomach upset, appearance of blood in the urine.

If you forget to take Cefalexin Oral Suspension

If you miss a dose, take the suspension as soon as you remember. If it is almost time to take the next dose, wait until then and then carry on as before. Do not take a double dose to make up for the 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, this medicine 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). Stop using cefalexin if you develop these symptoms and contact your doctor or seek medical attention immediately. 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 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)
- 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/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 CEFALLEXIN ORAL SUSPENSION

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

Dry powder: Store below 25°C, tightly closed in the container.

Made-up suspension: Store at 2 – 8°C. Discard any unused medicine after 14 days.

Do not use Cefalexin Oral Suspension after the expiry date stated on the pack.

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 Oral Suspension contains

The active substance is cefalexin monohydrate, 125mg or 250mg in a 5ml spoonful.

The other ingredients are sodium benzoate (E211). Disodium edetate, citric acid, sodium citrate, sorbitol powder, saccharin sodium, colloidal silicon dioxide, monoammonium glycerophosphate, and xanthan gum.

The 125mg/5ml suspension contains colour E127 (erythrosine) and strawberry flavour. The 250mg/5ml suspension contains colour 104 (quinoline yellow) and orange flavour.

What Cefalexin Oral Solution looks like and contents of the pack

125mg/5ml powder - pale pink, free flowing granular powder, which readily mixes in water to give a pink suspension with a flavour of strawberry.

250mg/5ml powder - pale yellow, free flowing granular powder, which readily mixes in water to give a yellow suspension with a flavour of orange.

Both suspensions are supplied in plastic bottles of 100ml.

Marketing Authorisation Holder

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