

Package leaflet: Information for the user

Keflex 125mg/5ml Powder for Oral Suspension & Keflex 250mg/5ml Powder for Oral Suspension
Cefalexin anhydrous

The name of your medicine is Keflex Powder for Oral Suspension 125mg & 250mg/5ml, which will be referred to as Keflex suspension throughout this document.

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 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 Keflex suspension is and what it is used for**
- 2. What you need to know before you take Keflex suspension**
- 3. How to take Keflex suspension**
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1 What Keflex suspension is and what it is used for

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

Do not take Keflex suspension if

- you are allergic (hypersensitive) to cefalexin, other cephalosporins (similar antibiotics) or any of the other ingredients (these are 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 Keflex suspension 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 Keflex
- 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
- are elderly

- have a central nervous system disorder

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

Long term use of Keflex may lead to infection with resistant bacteria and fungi.

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 Keflex and contact your doctor or seek medical attention immediately.

Other medicines and Keflex suspension

Please tell your doctor or pharmacist if you are taking any other medicines. This is especially important for the following, as they may interact with your Keflex 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 Keflex 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

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

Keflex suspension contains Allura Red AC (E129) which may cause allergic reactions.

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

Sucrose may be harmful to the teeth.

Every 5ml of Keflex suspension contains approximately 3g of sucrose. This should be taken into account if you have diabetes mellitus.

Keflex suspension contains sodium. This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium free'.

3 How to take Keflex suspension

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

The bottle is turned upside down and tapped to loosen the powder. Then a total of 60ml water in two portions is added, shaking after each addition until all the powder is in suspension. The suspension should be shaken well before use.

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

Dosage

Adults and the elderly

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

- Most infections can be treated by 500mg every 8 hours.
- For skin and soft tissue infections, sore throat (streptococcal pharyngitis), and mild infections of the urinary tract (e.g. cystitis), the usual dose is 250mg 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.

Use in children

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

- For skin and soft tissue infections, sore throat (streptococcal pharyngitis), and mild infections of the urinary tract (e.g. cystitis), the total daily dose may be divided and administered every 12 hours.

For most infections the following schedule is suggested:

Children under 5 years: 125mg every 8 hours.

Children 5 years and over: 250mg 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 medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. All medicines can cause allergic reactions, although serious allergic reactions are very rare.

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 or prolonged diarrhoea during or after taking Keflex. This could be a symptom of a more serious condition e.g. pseudomembranous colitis**
- **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:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Keflex suspension

Keep out of the sight and reach of children.

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

Powder: Do not store above 25°C. Keep the bottle tightly closed and in the outer carton.

After mixing, Keflex suspension should be stored in a refrigerator (2°C-8°C) and be used within 10 days.

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 to protect the environment.

6 Contents of the pack and other information

What Keflex suspension contains

The active substance in Keflex 125mg/5ml Powder for Oral Suspension is 125mg cefalexin anhydrous (as the monohydrate) per 5ml of suspension.

The active substance in Keflex 250mg/5ml Powder for Oral Suspension is 250mg cefalexin anhydrous (as the monohydrate) per 5ml of suspension.

The other ingredients are:

sucrose, imitation guarana flavour, Allura Red AC (E129), sodium laurilsulfate (E487), methylcellulose, dimeticone, xanthan gum (E415) and pregelatinised starch

What Keflex suspension looks like and contents of the pack

100ml plastic bottle with a screw cap, containing a white powder. When made into a suspension the medicine is coloured red.

Marketing Authorisation Holder

Flynn Pharma Ltd

5th Floor,

40 Mespil Road, Dublin 4,

IRELAND, D04 C2N4

Manufacturer

ACS DOBFAR S.p.a

Via Laurentina,

Km 24,730, Pomezia

00071
Rome
Italy

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