

Package leaflet: Information for the user

Keflex Tablets and Capsules 250mg & 500mg

Cefalexin

The name of your medicine is Keflex Tablets and Capsules 250mg and 500mg, which will be referred to as Keflex throughout this document.

Read all of this leaflet carefully before you start taking this medicine.

- 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, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1 What Keflex is and what it is used for

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

Keflex 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 Before you take Keflex

Do not take Keflex 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.

Take special care with Keflex if you

- have had an allergic reaction to cefalexin, cephalosporins, penicillins, or other drugs in the past
- develop diarrhoea
- have a severe kidney disorder (you may need a reduced dose).

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription. This is especially important of the following, as they may interact with your Keflex:

- 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 and your doctor will be able to decide what is suitable for you.

Pregnancy and breast-feeding

You should tell your doctor if you are pregnant or breast-feeding. Ask your doctor or pharmacist before taking any medication.

Driving and using machines

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

3 How to take Keflex

Always take Keflex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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, uncomplicated urinary tract infections, 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.

The usual **total daily dose for children** is 25-50mg/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: 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 product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Keflex 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 diarrhoea.

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)
- itching of the vagina or anus caused by thrush (candidiasis).

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

5 How to store Keflex

Keep out of the sight and reach of children.

Tablets and capsules:

Do not store above 30°C.

Keep containers tightly closed.

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 Keflex contains

The active substance is cefalexin monohydrate.

The other ingredients are:

sodium starch glycollate type A, pregelatinised maize starch (250mg tablet only), starch dry-flow (250mg tablet only), stearic acid (250mg tablet only), maize starch (250mg tablet only), magnesium stearate, povidone (500mg tablet only), methylhydroxypropylcellulose, glycerol, talc, titanium dioxide, iron oxide yellow, iron oxide red, cellulose with sodium carboxymethylcellulose, dimeticone, magnesium stearate, patent blue V, quinoline yellow, titanium dioxide, gelatin.

What Keflex looks like and contents of the pack

Tablets:

Plastic bottles of 20, 100 and 500 tablets, or blister strips of 28 tablets. The 500mg tablets may be packed into blisters of 3, 4, 21 or 28 tablets.

Capsules:

Plastic bottles of 20, 100 and 500 capsules, or blister strips of 28 capsules. The 500mg capsules may be packed into blisters of 21 or 28 capsules.

250mg tablets are peach and marked GP3.

500mg tablets are peach and marked GP4.

250mg capsules are green and white and marked GP1.

500mg capsules are pale green and dark green and marked GP2.

Not all pack sizes may be marketed.

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