

Package leaflet: Information for the user

Keflex® 250 mg Hard Capsules (cefalexin anhydrous)

The name of your medicine is Keflex 250 mg hard capsules, which will be referred to as Keflex 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 is and what it is used for
2. What you need to know before you take Keflex
3. How to take Keflex
4. Possible side effects
5. How to store Keflex
6. Contents of the pack and other information

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. What you need to know 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Keflex 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.

Tell your doctor if you are having blood or urine tests. Keflex 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

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:

- 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 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.

3. How to take Keflex

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

Dosage

Adults and the elderly

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

- Most infections can be treated with 500 mg 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 250 mg every 6 hours, or 500 mg 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 25-50 mg/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: 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.

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)
- 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, Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971 Fax: +353 1 6762517

Website: www.hpra.ie E-mail: medsafety@hpra.ie

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

5. How to store Keflex

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

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

Do not store above 30°C.

Store in the original package.

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 protect the environment.

6. Contents of the pack and other information

What Keflex contains

The active substance is cefalexin anhydrous.

Each capsule contains 250 mg cefalexin anhydrous (as the monohydrate).

The other ingredients are:

cellulose with sodium carboxymethylcellulose, magnesium stearate and dimeticone.

The gelatin capsules are coloured with patent blue V (E131), quinoline yellow (E104) and titanium dioxide (E171).

The printing ink contains shellac and black iron oxide (E172).

What Keflex looks like and contents of the pack

The capsules are green and white, marked GP1.

Keflex is available in blister packs of 28 capsules (2 aluminium blister strips of 14 capsules) in an over labelled outer carton.

Manufacturer

Manufactured by: Facta Farmaceutici SpA,
Via Laurentina, Km 24,730 Pomezia 00040, Rome, Italy.

Procured from within the EU and repackaged by:

Doncaster Pharmaceuticals Group Ltd.,
Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park,
Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2,
North Ring Business Park, Santry, Dublin 9.

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Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0) 1302 365000
(Regulatory)

Please be ready to give the following information:

Product name: Keflex 250 mg Hard Capsules

Reference No: 1151/166/001