

## PATIENT INFORMATION LEAFLET

# KEFLEX<sup>®</sup> 500mg Film-coated Tablets

cefalexin anhydrous (as monohydrate)

The name of your medicine is Keflex 500mg Tablets, 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.

### In this leaflet

1. What Keflex is and what it is used for
2. What you need to know before you take Keflex
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#### 1. What Keflex is and what it is used for

Keflex contains the active ingredient cefalexin, 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 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).

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 interaction with resistant bacteria and fungi.

### Other medicines and Keflex

Please tell your doctor or pharmacist if you are taking any other medicines. This is especially important of 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 alright 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 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 1-4g 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.

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

### **The following side effects have been reported**

- Diarrhoea
- Feeling sick (nausea)
- Vomiting
- Indigestion
- Stomach pains
- Measle-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.

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

Do not store above 30° C.

Keep in the original package.

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 further information**

#### **What Keflex contains**

The active substance in Keflex 500 mg tablets is: 500mg cefalexin anhydrous (as monohydrate).

The other ingredients are: sodium starch glycollate, magnesium stearate and povidone. The tablets coating contains: methylehydroxypropylcellulose, glycerol and talc and are coloured with titanium dioxide (E171) and red and yellow oxide (E172).

#### **What Keflex looks like and contents of the pack**

**Keflex 500mg tablets** are peach coloured and pillow-shaped, marked GP4.

**Pack size:** Keflex 500mg tablets are available in blister packs of 21.

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

**Parallel Product Authorisation number:** PPA 465/010/3

**Product procured from within the EU by the Parallel Product Authorisation holder and repackaged by:** PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

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