

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Keftid 250 mg and 500 mg Capsules

## Cefaclor (as Monohydrate)

**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 Keftid is and what it is used for
2. Before you take Keftid Capsules
3. How to take Keftid Capsules
4. Possible side effects
5. How to store Keftid Capsules
6. Further information

## **1. WHAT KEFTID IS AND WHAT IT IS USED FOR**

This medicine is called Keftid Capsules. Keftid Capsules contain the active substance cefaclor, which belongs to a group of medicines called cephalosporin antibiotics.

Cefaclor is used to kill bacteria that cause infections in your body. These include throat, chest and ear infections, sinus infections and infections of the skin.

## **2. BEFORE YOU TAKE KEFTID CAPSULES**

### **Do not take Keftid Capsules**

- if you are allergic (hypersensitive) to any cephalosporin antibiotic, such as cefalexin, cefuroxime, cefradine or cefaclor
- if you are allergic to any of the other ingredients of Keftid Capsules

Talk to your doctor before taking this product if any of the above apply to you.

Keftid should not be given to infants under 1 month old.

### **Take special care with Keftid Capsules**

- if you are allergic to any penicillin antibiotic, such as penicillin, ampicillin, amoxicillin or flucloxacillin
- if you have ever suffered from colitis (an inflammation of the bowel)
- if you suffer from any kidney problems
- if you are on kidney dialysis
- if you are diabetic (cefaclor can interfere with some urine sugar tests)

If any of the above apply to you, it is important that you tell your doctor or pharmacist before taking Keftid Capsules and they will decide what to do. It may still be safe for you to take Keftid Capsules.

If you are having a blood test, it is important to tell your doctor that you are taking this medicine as it may affect the result.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any medicines, including those medicines obtained without a prescription.

This is especially important if you are taking:

- warfarin (used to thin the blood)
- a medicine called probenecid (used to treat gout)
- combined oral contraceptives (Keftid Capsules may reduce the effectiveness of combined oral contraceptives)

It may still be safe for you to take Keftid Capsules; your doctor or pharmacist will be able to advise you further.

### **Pregnancy and breast-feeding**

If you are pregnant, think you might be pregnant, or are breast-feeding, you should ask your doctor or pharmacist for advice before taking Keftid or any other medicine.

### **Driving and using machines**

Keftid Capsules should not affect your ability to drive and use machines.

## **3. HOW TO TAKE KEFTID CAPSULES**

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

Keftid Capsules should be taken by mouth (orally).

The usual dose for adults and the elderly is 250mg every eight hours. In more severe infections the dosage may be doubled to 500mg every eight hours.

The usual dose for children will depend on the child's weight. Babies less than one month old should not be given cefaclor.

Doctors sometimes prescribe different doses to these. It is important to read the label on your medicine, as it will tell you precisely what dose to take.

### **If you take more Keftid Capsules than you should**

If you take too many capsules contact your nearest hospital casualty department or tell your doctor or pharmacist immediately. Take this leaflet and any remaining capsules with you.

### **If you forget to take Keftid Capsules**

If you forget to take your medicine, just take your normal dose as soon as you remember and then continue as before. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Keftid Capsules**

Keep taking the medicine until you have finished the full course of treatment that your doctor has prescribed for you. Do not stop taking the medicine, even if you feel better. This will make sure that the infection has completely cleared.

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

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Keftid Capsules can cause side effects, although not everybody gets them.

If you get any of the following side effects you should stop taking Keftid and tell your doctor immediately or go to the casualty department of your nearest hospital, as these may be signs of a serious allergic reaction:

- a skin rash resembling hives or nettle rash
- a severe skin rash with flushing, fever, blisters and ulcers (Steven Johnsons Syndrome).
- a severe skin disorder with severe peeling of the skin, painful red areas, blistering, fever, pain and discomfort (Toxic Epidermal Necrolysis).
- itchy and/or scaly skin
- red or purple patches on the skin
- joint pain
- difficulty breathing or wheezing
- fever
- swelling of the tongue, face, lips or throat
- feeling faint accompanied by one or some of the other reactions above

Tell your doctor immediately if you notice the following as you may require urgent medical attention:

- diarrhoea which becomes severe or contains blood or mucus

Other side effects of Keftid Capsules include:

- diarrhoea
- feeling sick or being sick
- stomach discomfort
- headache
- kidney problems
- jaundice (yellowing of the skin and the whites of the eyes)
- dizziness
- drowsiness
- nervousness
- confusion
- difficulty sleeping
- muscle tightness
- hyperactivity

- liver problems
- seeing and hearing things which are not there (hallucinations)
- genital itching
- irritation or inflammation of the vagina

Very rarely this medicine may lower the levels of certain blood cells, these will return to normal when you stop taking Keftid Capsules (symptoms may include sore throat, mouth ulcers, bruising more easily than normal, bleeding, tiredness, mouth ulcers and feeling weak).

If you consider any of these side effects to be serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE KEFTID CAPSULES**

Keep out of the reach and sight of children.

Do not use Keftid Capsules after the expiry date, which is stated on the carton and blister foil. The expiry date refers to the last day of that month.

Store your capsules below 25°C. Store in the original packaging.

Do not use Keftid Capsules if you notice that the pack or any of the capsules are damaged.

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 Keftid Capsules contain**

The active substance in Keftid Capsules is called cefaclor. The capsules contain either 250mg or 500mg of cefaclor as cefaclor monohydrate. The other ingredients are pregelatinised maize starch, silica colloidal hydrated and magnesium stearate. The capsule shells are made of gelatin and contain indigotine (E132), erythrosine (E127), black ferric oxide (E172) and

titanium dioxide (E171) as colouring agents. The printing ink on the capsule shells contains shellac, propylene glycol, strong ammonia solution and yellow iron oxide (E172).

### **What Keftid Capsules look like and the contents of the pack**

Keftid Capsules 250mg are purple and white hard gelatin capsules with 'CEF250' printed in gold. Keftid Capsules 500mg are purple and grey hard gelatin capsules with 'CEF500' printed in gold.

Keftid Capsules 250mg and 500mg are available in packs containing 21 and 50 capsules.

### **Marketing Authorisation Holder**

Co-pharma Limited  
Unit 4, Metro Centre,  
Tolpits Lane  
Watford Herts  
WD18 9SS  
United Kingdom

### **Manufactured by:**

Almac Pharma Services Ltd  
Almac House  
20 Seagoe Industrial Estate  
Craigavon  
BT63 5QD  
United Kingdom

Date of leaflet preparation: November 2012  
Keftid is a trademark.