For oral administration. Fach 5ml of reconstituted suspension contains cefaclor monohydrate Ph Eur equivalen to 125mg of cefaclor. Other ingredients include: sodium benzoate, Allura Red (E129), sorbitol and aspartame. Keep all medicines out of the reach of children. PA 894/4/3

MA Holder:

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KEFtid

125ma/5ml SUSPENSION Cefaclor (as monohydrate)

Sugar-Free

To the patient: Take regularly as directed by the physician. Shake well before use. Do not dilute unless instructed. Keep the reconstituted suspension in the fridge (between 2 and 8°C) with the lid tightly closed, Throw away any suspension that you haven't used after 14 days. To the pharmacist: Powder for cefaclor oral suspension 125ma/5ml. To dispense, add 84ml water, invert bottle and shake well. Store below 25°C in a dry place. PL1135

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PACKAGE LEAFLET: INFORMATION FOR THE USER Keftid 125mg/5ml powder for oral suspension and Keftid 250mg/5ml powder for oral suspenion 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 Suspension 3. How to take Keftid Suspension

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4. Possible side effects

5. How to store Keftid Suspension 6. Further information

1. WHAT KEFTID IS AND WHAT IT IS USED FOR

The name of this medicine is Keftid Suspension, Keftid Suspension contains the active substance cefactor, which belongs to a group of medicines called cenhalosporin antibiotics

Cefactor 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 SUSPENSION

Do not take Keftid Suspension

- 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 Suspension

- if you have a metabolic disorder called phenylketonuria

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 Suspension

- if you are allergic to any penicillin antibiotic, such as penicillin, ampicillin, amoxicillin or flucloxicillin
- 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 Suspension and they will decide what to do. It may still be safe for you to take Keftid Suspension.

If you are having a blood test, it is important that you 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

This is especially important if you are taking:

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

It may still be safe for you to take Keftid Suspension; 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 Suspension should not affect your ability to drive and use machines.

Important information about some of the ingredients of Keftid Suspension Keftid Suspension contains aspartame (E951), a source of phenylalanine. This may be harmful for people with phenylketonuria. If you have phenylkétonuria, do not také Keftid Suspension. Please speak to your doctor for further advice.

Keftid Suspension contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Keftid Suspension contains allura red (E129), this may cause allergic

3. HOW TO TAKE KEFTID SUSPENSION

Always take Keftid Suspension exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Keftid Suspension should be taken orally (by mouth).

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

If you take more Keftid Suspension than you should

f you take too much Keftid Suspension contact your nearest hospital casualty department or tell your doctor or pharmacist immediately. Take this leaflet and any remaining suspension with you.

If you forget to take Keftid Suspension

If you forget to take your Keftid Suspension, 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 Suspension

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.

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4. POSSIBLE SIDE EFFECTS

Like all medicines, Keftid Suspension 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
- difficulty breathing or wheezing

- · 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 symptoms as you may require urgent medical attention:
- · diarrhoea which becomes severe or contains blood or mucus

Other side effects of Keftid include:

- · feeling sick or being sick
- stomach discomfor
- headache
- kidnev problems
- · jaundice (yellowing of the skin and the whites of the eyes)
- · seeing and hearing things which are not there (hallucinations)

- dizziness drowsiness
- nervousness confusion
 - difficulty sleeping
 - muscle tightness
 - hyperactivity
 - · 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 Suspension (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 SUSPENSION

Keep out of the reach and sight of children. Keftid Suspension is a dry powder for reconstitution with water. The dry powder should be stored in a dry place below 25°C.
Store your reconstituted Keftid Suspension in the refridgerator (2 - 8°C). Store in the original bottle, with the lid tightly closed. Dispose of any suspension that has not been taken after 14 days.

Your pharmacist should not prepare Keftid Suspension after the expiry date. which is stated on the label. This will be the last day of the month stated.

Do not use Keftid Suspension if you notice that the bottle is damaged or if the suspension appears to have deteriorated. 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 Suspension contains The active substance in Keftid Suspension is called cefaclor. Each 5ml of suspension contains either 125 mg or 250 mg of cefaclor as

cefaclor monohydrate. The other ingredients in the suspension are sodium benzoate, silica colloidal anhydrous, xanthan gum, sorbitol (E420), aspartame (E951), citric acid (anhydrous), strawberry flavour, banana flavour, pineapple flavour, raspberry flavour, taste modifier and allura

What Keftid Suspension looks like and the contents of the pack Keftid Suspension is available as a white to slightly pink coloured dry

powder for the preparation of a pink fruit flavoured suspension. When prepared by the pharmacist, each bottle of suspension contains 100ml.

Marketing Authorisation Holder:

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

Manufactured by:

Almac Pharma Services Limited Almac House 20 Seagoe Industrial estate Craigavon BT63 50D United Kinadom

Date of leaflet preparation: November 2012

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For oral administration.

Each 5ml of reconstituted

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