

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

(KEFROX) Cefuroxime Axetil Oral Suspension 125 mg/5 ml

Cefuroxime Axetil

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 health care provider.
- 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What KEFROX Oral Suspension is and what it is used for
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1. WHAT KEFROX ORAL SUSPENSION IS AND WHAT IT IS USED FOR

Each 5ml spoonful of KEFROX Oral Suspension contains Cefuroxime 125mg. KEFROX Oral Suspension is used to treat infections of the chest, ear, nose, throat, urinary tract, skin and is also used to treat gonorrhoea and Lyme disease.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE KEFROX ORAL SUSPENSION

Do not take KEFROX Oral Suspension if;

- You are allergic or sensitive to any of the ingredients or if you have experienced allergy to other cephalosporin based antibiotics.

Cautions before you take KEFROX ORAL SUSPENSION

Cephalosporin antibiotics may, in general, be given safely to patients who are hypersensitive to penicillins, although cross-reactions have been reported. Special care is indicated in patients who have experience an anaphylactic reaction to penicillin.

KEFROX Oral Suspension contains aspartame. Therefore if you suffer from PKU (Phenylketonuria) aspartame will be converted to phenylalanine in the body and may affect you. Discuss this with your doctor before starting treatment.

Interactions with other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Medicines used to reduce the amount of acid in your stomach (e.g. antacids used to treat heartburn) can affect how KEFROX Oral Suspension works. Tell your doctor or pharmacist if you are taking any medicine like Probenecid Oral anticoagulants for the treatment of gout.

Ask your doctor for advice if you are taking contraceptive pills. KEFROX Oral Suspension may reduce the effectiveness of the contraceptive pill. If you are taking the contraceptive pill while you are being treated with KEFROX Oral Suspension you also need to use a barrier method of contraception (such as condoms).

Taking KEFROX Oral Suspension with food and drink

KEFROX Oral Suspension must be taken after food to improve treatment.

Pregnancy and breast-feeding

As with all medicines, KEFROX Oral Suspension should be used with caution during pregnancy and whilst breastfeeding. If you are planning a pregnancy, pregnant or breast feeding, do not use this medicine until you have talked to your doctor.

Driving and using machines

KEFROX Oral Suspension can make you dizzy and have other side effects that make you less alert. Don't drive or use machines if you do not feel well.

3. HOW TO TAKE KEFROX ORAL SUSPENSION

Your doctor will have decided the dosage and length of treatment that is suitable for your condition. Always follow your doctor's instructions. Ensure that you finish the entire course of antibiotics to clear the infection completely as stopping treatment early may cause your infection to return.

Generally, the normal dose is 125mg (one 5ml spoonful) twice a day for children and 250mg (two 5ml spoonfuls) twice a day for adults, for seven days. Children over 2 years who have a more severe infection can be given up to 250mg (two 5ml spoonful twice a day). Lyme disease in adults and children over 12 is treated by taking 500mg (four 5ml spoonfuls) twice a day up to 20 days. Gonorrhoea is treated by taking a single dose of 1 gram (eight 5ml spoonfuls).

KEFROX Oral Suspension is not recommended for children aged under 3 months, as the safety and effectiveness are not known in this age group.

If you take more KEFROX Oral Suspension then you should

Contact your nearest casualty department immediately in case of overdose. If you take too much KEFROX Oral Suspension you may have neurological disorders, in particular you may be more likely to have fits (seizures).

If you forget to take KEFROX Oral Suspension

If you forget a dose, take it as soon as you remember unless it is time for the next dose. Do not take two doses at the same time.

If you have any further questions on the use of this product, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, KEFROX Oral Suspension can cause side effects, although not everybody gets them. Very rarely, KEFROX Oral Suspension can cause an allergic reaction in susceptible individuals, which usually causes swelling of the neck, face and lips, breathing difficulties, tightness of the chest, skin rashes, fever or blistering of the skin. If this happens you should stop using this medicine straight away and immediately seek medical advice. If you experience any other unusual side effects, such as nausea, diarrhea (especially if bloody), headache, jaundice or unexpected changes in the appearance of your urine, inform your doctor or pharmacist at once.

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

5. HOW TO STORE KEFROX ORAL SUSPENSION

Keep out of the reach and sight of children. Store in the original carton and away from light. Unreconstituted suspension should be stored in a cool dry place below 25 °C. Store the reconstituted suspension in the fridge and discard any unused suspension 7 days after reconstitution. Do not use KEFROX Oral Suspension after the expiry date which is stated on the carton after 'Exp'. KEFROX Oral Suspension 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 KEFROX Oral Suspension contains:

The active pharmaceutical ingredient is Cefuroxime Axetil.

The other ingredients (excipients) are Colloidal silicon dioxide, Xanthan gum, Aspartame, Sodium citrate anhydrous, Sodium chloride (Dried), Saccharin Sodium, Sodium benzoate, Flavour Powder Sweet Banana and Flavour Powder Strawberry.

What KEFROX Oral Suspension looks like and contents of the pack:

KEFROX Oral Suspension 125 mg/5 ml consists of white coloured granules which become a yellow coloured solution after reconstitution. The suspension is supplied in an HDPE Tapering bottle containing 70 ml of the 125 mg/5 ml suspension. This medicine must be made up with water using the original granules that were supplied in the bottle. The bottle is contained within a carton, together with an insert.

Manufacturer

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