

## PACKAGE LEAFLET: INFORMATION FOR THE USER

---

### CEFACLOR ALKALOID

125mg/5ml and 250mg/5ml Suspension

#### CEFACLOR MONOHYDRATE

---

*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 only • 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 •*

---

#### What is in this leaflet?

1. What Cefaclor is and what it is used for
2. Before you take Cefaclor Suspension
3. How to take Cefaclor Suspension
4. Possible side effects
5. How to store Cefaclor Suspension

#### 1. WHAT CEFACLOR IS AND WHAT IT IS USED FOR

The name of this medicine is Cefaclor Suspension. Cefaclor Suspension contains 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, infections of the skin and soft tissue and urinary tract infections.

#### 2. BEFORE YOU TAKE CEFACLOR SUSPENSION Do not take Cefaclor 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 Cefaclor Suspension
- if you suffer from porphyria (a rare inherited disorder which affects the blood)
- if you have a metabolic disorder called phenylketonuria

Talk to your doctor before taking this product if any of the above apply to you. Cefaclor should not be given to infants under 1 month old.

#### Take special care with Cefaclor Suspension

- 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 Cefaclor Suspension and they will decide what to do. It may still be safe for you to take Cefaclor 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 prescription.

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 (Cefaclor Suspension may reduce the effectiveness of combined oral contraceptives)

It may still be safe for you to take Cefaclor 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 Cefaclor or any other medicine.

### ***Driving and using machines***

Cefaclor Suspension should not affect your ability to drive and use machines.

Important information for patients with phenylketonuria or an intolerance to some sugars

Cefaclor Suspension contains aspartame (E951), a source of phenylalanine. This may be harmful for people with phenylketonuria. If you have phenylketonuria, do not take Cefaclor Suspension. Please speak to your doctor for further advice.

Cefaclor Suspension contains sorbitol (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## ***3. HOW TO TAKE CEACLOR SUSPENSION***

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

Cefaclor Suspension 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 Cefaclor Suspension than you should***

If you take too much Cefaclor 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 Cefaclor Suspension***

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 Cefaclor 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.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Cefaclor Suspension can cause side effects, although not everybody gets them.

If you get any of the following side effects you should stop taking Cefaclor 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:

- severe skin reactions such as Stevens- Johnson Syndrome- symptoms of a rash with flushing, fever, blisters and ulcers, and Toxic Epidermal Necrolysis- symptoms of reddening, peeling and swelling of the skin that resembles burns.
- other skin reactions including itching and red or purple patches
- 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 symptoms as you may require urgent medical attention:

- diarrhoea which becomes severe or contains blood or mucus

**Rare** (affects 1 to 10 users in 10,000)

This medicine may lower the levels of certain blood cells, these will return to normal when you stop taking Cefaclor Suspension (symptoms may include sore throat, mouth ulcers or feeling weak).

Other rare side effects are kidney problems, raised liver enzymes (which will be seen in a blood test).

**Common** (affects 1 to 10 users in 100): headache, stomach discomfort, feeling (nausea) or being sick (vomiting), diarrhoea.

**Not known** (frequency cannot be estimated from the available data): genital itching, irritation or inflammation of the vagina, confusion, nervousness, difficulty sleeping, muscle tightness, hyperactivity, seeing and hearing things which are not there (hallucinations), dizziness, drowsiness, jaundice (yellowing of the skin and the whites of the eyes), liver problems, positive Coomb's test.

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 CEFACTOR SUSPENSION*

Keep out of the reach and sight of children.

Store your Cefaclor Suspension in a refrigerator (between 2oC and 8oC). 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 Cefaclor Suspension after the expiry date, which is stated on the label.

Do not use Cefaclor 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.

**This leaflet was last approved in December 2011**