

PATIENT INFORMATION LEAFLET
CEFAZIM-DS SUSPENSION (Cefixime for Oral Suspension USP 100 mg)
[Cefixime Trihydrate USP]

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

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1. What Cefazim-DS Suspension is and what it is used for

Cefazim-DS Suspension is indicated for the treatment of the following infections caused by sensitive agents:

Acute otitis media

Upper respiratory tract infections (pharyngitis, tonsillitis, acute sinusitis)

Lower respiratory tract infections (acute exacerbations of chronic bronchitis and community-acquired pneumonia)

Urinary tract infections (acute cystitis and uncomplicated acute pyelonephritis) Uncomplicated gonococcal urethritis and cervicitis.

National and/or local guidance on the appropriate use of antibiotics should be taken into account.

2. Before you take Cefazim-DS Suspension

Do not take Cefazim-DS Suspension:

If you are allergic to cefixime or any other component of this medicine (listed in section 6).

If you are allergic (hypersensitivity) to any other cephalosporin.

If you have ever had an allergic reaction to penicillin or beta-lactam antibiotics.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Cefazim-DS Suspension

Take special care with Cefazim-DS Suspension: - If you have previously suffered any type of allergic reaction to medicines, especially to antibiotics such as cephalosporins or penicillins. Treatment with cefixime should be suspended if any allergic reaction appears.

- If you suffer from kidney failure or are on dialysis. In both cases you can take Cefixime Suspension but at a lower dosage.

- If you experience severe diarrhea, stomach pain, cramps or if you notice blood, mucus or pus in the stool, you should immediately report this to your doctor. Medicines that can slow or stop bowel movements (peristaltic) should not be taken.

Prolonged use of cefixime can cause the growth of resistant microorganisms. In this case, your doctor will decide whether stopping treatment is necessary.

Effect on laboratory tests

Like other cephalosporins, this medicine can cause false positive reactions in laboratory tests to determine ketones and glucose in urine (Benedict's or Fehling's test, widely used by diabetics, so they should inform the doctor that they are taking taking Cefixime) and the Coombs reaction (antibody test).

Other medicines and Cefazim-DS Suspension

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

You should not take this medicine together with other antibiotics without express advice from your doctor.

Tell your doctor or pharmacist if you are taking an anticoagulant medicine such as warfarin.

Cefazim-DS Suspension with food and drink Cefazim-DS Suspension can be taken with or without food. The tablets should be swallowed whole, without chewing and accompanied by a little liquid.

The reconstituted suspension can be diluted with water.

Pregnancy and breast - feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

There is no information available about the possible negative effects of cefixime during pregnancy, so its use is not recommended unless your doctor considers it appropriate.

The use of cefixime during breastfeeding is not recommended, as there is no data available on its passage into breast milk.

Driving and using machines Cefazim-DS Suspension does not normally affect the ability to use and drive machines. However, if you feel dizzy, do not drive or use machines.

Cefixime Suspension 100 mg/5 ml powder for oral suspension contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Cefixime Suspension 100 mg/5 ml powder for oral suspension contains less than 1 mmol (23 mg) sodium per ml, that is, it is practically "sodium-free".

This medicine contains 0.526 mg of sodium benzoate per ml.

3. How to take Cefazim-DS Suspension

Take this medicine exactly as your doctor tells you. Talk to your doctor or pharmacist if you have any questions.

Dosage

The usually recommended dosage is as follows:

Adults and adolescents over 11 years old (or over 30 kg in weight)

The recommended dose for adults is 200 mg at a time, every 12 hours or 400 mg per day, administered at once.

For uncomplicated urinary tract infections, a dose of 200 mg per day is effective.

Elderly

The recommended dose for elderly patients is the same dose as for adults, unless there is severe renal insufficiency (see below).

Renal failure

Cefixime Suspension can be administered to adult patients with renal failure. In patients with creatinine clearance equal to or greater than 20 ml/min, use the doses indicated above. If creatinine clearance is less than 20 ml/min, it is advisable not to exceed a dose of 200 mg/ day. This dose should also not be exceeded in patients on chronic peritoneal dialysis or hemodialysis, as cefixime is very slowly removed from circulation by dialysis. There is not enough information about the use of cefixime in pediatrics and adolescents with renal failure. The use of cefixime in these groups of patients is not recommended

Cefixime Suspension 100 mg/5 ml powder for oral suspension

Preparation of the oral suspension: shake the powder in the bottle until it becomes loose. Add 4 measuring spoons of water. Stopper and shake vigorously. Add more water until you reach mark 4 indicated on the label. Shake until obtaining a uniform suspension.

The usually recommended dose is:

Use in children

- Cefixime Suspension 100 mg/5 ml powder for oral suspension: 8 mg/kg per day in a single dose.

In terms of reconstituted suspension, the dosage is generally as follows:

- Children aged 2 to 4 years: 1 measuring spoon per day or ½ measuring spoon if administered every 12 hours.
- Children aged 5 to 8: 2 measuring spoons per day or 1 measuring spoon every 12 hours.
- Children aged 9 to 12 years: 3 measuring spoons per day or 1+½ measuring spoons if administered every 12/12 hours.

If you take more Cefazim-DS Suspension than you should

There is no information on cases of overdose. Doses of 2 g to healthy adults caused moderate gastrointestinal effects of the type seen with therapeutic doses.

In case of acute poisoning, diarrhea, vomiting and abdominal pain can be expected.

There are no specific antidotes. Gastric lavage can be performed (if ingestion was less than 2 hours ago) and the patient must be hydrated, electrolytic ally rebalanced, if necessary.

Peritoneal dialysis and hemodialysis do not remove clinically significant amounts of the antibiotic from the blood.

If you experience any of these symptoms, you should contact your doctor or nearest hospital immediately. Take this leaflet with you.

If you forget to take Cefazim-DS Suspension

Do not take a double dose to make up for a dose you forgot to take.

If you forget to take your dose on time,

Take it as soon as you remember.

If it is almost time to take your next dose, wait until then and proceed as before.

If you stop taking Cefazim-DS Suspension

Your doctor will tell you the duration of your treatment with Cefixime Suspension. Do not suspend treatment before the indicated period as you would feel the symptoms before they started.

If you still have questions about the use of this medicine, talk to your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most of the side effects observed are mild and transient.

The following side effects require immediate action if you experience them. You should stop taking Cefixime Suspension and consult your doctor immediately if the following symptoms occur:

Rare side effects (affecting less than 1 in 1000 patients) include:

- Swelling of the face, tongue and difficulty breathing.

Very rare side effects (affecting less than 1 in 10,000 patients) include:

- Severe diarrhea that may contain blood;
- Unexpected allergic reaction accompanied by shortness of breath, skin rash, difficulty breathing, drop in blood pressure;
- Erythematous, severe and extensive skin rash.

The following side effects have also been reported:

Common side effects (affecting less than 1 in 10 patients): - Diarrhea.

Uncommon side effects (affecting less than 1 in 100 patients):

- Headache;
- Stomach (abdominal) pain;
- Nausea;
- Vomiting;
- Rash;
- Increase in serum liver enzymes (transaminases, alkaline phosphatases).

Rare side effects (affecting less than 1 in 1000 patients):

- Bacterial superinfection;
- Fungal superinfection;
- Eosinophilia;
- Hypersensitivity;
- Dizziness;
- Flatulence;
- Hepatitis;
- Jaundice;
- Angioneurotic edema;

- Pruritis;
- Inflammation of the mucous membranes;
- Fever;
- Increased serum urea;

Very rare side effects: (affecting less than 1 in 10,000 patients):

- Antibiotic- associated colitis;
- Anaphylactic shock;
- Rheumatoid arthritis;

- Psychomotor hyperactivity;
- Interstitial nephritis;
- Increase in serum creatinine.

Reporting of side effects

If you get any side effects, including any possible side effects not listed in this leaflet, please talk to your doctor or pharmacist.

5. How to Store Cefazim-DS Suspension

Keep out of the reach and sight of children.

Before reconstitution store at temperature below 30°C. After reconstitution store the suspension at 5°C to 30°C.

Do not use Cefazim-DS Suspension after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

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 Cefixime for Oral Suspension USP 100 mg Contains:

The active substance(s) : Cefixime Trihydrate USP

Composition: After reconstitution each 5 mL contains:

Cefixime USP as Trihydrate

Eq. to Anhydrous Cefixime 100 mg

The other ingredients are:

- Colloidal Anhydrous Silica
- Sodium Benzoate
- Xanthan Gum
- Aspartame
- Sucrose
- Colour Sunset Yellow
- Trusil Orange Special Powder Flavor

What Cefazim-DS Suspension looks like and contents of the pack

Cefazim-DS Suspension is Light orange colored free flowing powder granules when reconstituted it gives light orange colored suspension.

Pack size: 30 mL HDPE Bottle.

Name and full physical address of Marketing Authorization Holder and Manufacturing site:

ZIM LABORATORIES LIMITED

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