

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Ceroxim® 250 Tablets

Ceroxim® 500 Tablets

Ceroxim® Suspension

Ceroxim® Forte Suspension

Read all of this leaflet carefully before you start taking or giving Ceroxim

- *Keep this leaflet. You may need to read it again.*
- *If you have further questions, please ask your doctor or your pharmacist.*
- **Ceroxim** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT CEROXIM CONTAINS

The active substance in your medicine is a cephalosporin antibiotic called cefuroxime (present as cefuroxime axetil).

Ceroxim 250 Tablets

Each tablet contains:

Cefuroxime axetil equivalent to cefuroxime 250 mg

Contains sugar: Sucrose 40 mg.

Ceroxim 500 Tablets

Each tablet contains:

Cefuroxime axetil equivalent to cefuroxime 500 mg

Contains sugar: Sucrose 80 mg.

Ceroxim Suspension

Each 5 ml of constituted suspension contains:

Cefuroxime axetil equivalent to cefuroxime 125 mg

Contains sugar: Sucrose 2,8 g.

Preservative: Sodium benzoate 0,2 % *m/v*

Ceroxim Forte Suspension

Each 5 ml of constituted suspension contains:

Cefuroxime axetil equivalent to cefuroxime 250 mg

Contains sugar: Sucrose 2,5 g.

Preservative: Sodium benzoate 0,2 % *m/v*

The other ingredients in **Ceroxim Tablets** are: calcium carbonate, colloidal anhydrous silica (Aerosil-200), croscarmellose sodium, microcrystalline cellulose, monosodium citrate, povidone (K-30), purified water, sodium lauryl sulphate, stearic acid and sucrose.

The other ingredients in **Ceroxim / Ceroxim Forte Suspension** are: aspartame, flavour peppermint, flavour tutti fruti, mannitol, mono sodium citrate, silica colloidal hydrated, sodium chloride and xanthan gum.

2. WHAT CEROXIM IS USED FOR

Ceroxim belongs to a group of medicines known as antibiotics which help the body fight infections by killing certain bacteria that cause infection.

Ceroxim is used for the treatment of various bacterial infections.

3. BEFORE YOU TAKE OR GIVE CEROXIM

Do not take or give Ceroxim if:

- You or your child are hypersensitive (allergic) to cefuroxime axetil, other cephalosporin antibiotics or any of the other ingredients of **Ceroxim** listed under the heading “**WHAT CEROXIM CONTAINS**”.
- You or your child previously have had an allergic reaction to penicillin antibiotics (such as piperacillin, ticarcillin, ampicillin, amoxicillin, oxacillin, cloxacillin, flucloxacillin, nafcillin etc.); you may also be allergic to **Ceroxim**. You should be strictly monitored while taking **Ceroxim**.

Take special care with Ceroxim and talk to your doctor if:

- You or your child have a history of gastro-intestinal (stomach-intestinal) conditions, especially ulcerative colitis (ulceration of the colon), pseudomembranous (‘false membrane’) colitis or enteritis (inflammation of the intestine)
- Renal impairment – a smaller dose may be needed
- Porphyria – safety has not yet been evaluated.

Please inform your doctor before taking or giving **Ceroxim**, even if these statements were applicable to you at any time in the past.

If you or your child have any symptoms, such as allergic reactions, fungal infections in the mouth (thrush) or vagina (vaginitis) caused by an overgrowth of yeast (*Candida*), stomach cramps, abdominal tenderness, severe and watery diarrhoea (*pseudomembranus colitis*) while you are taking or giving **Ceroxim**. Stop taking or giving **Ceroxim** and contact your doctor or pharmacist immediately if these symptoms occur.

Laboratory Tests

Ceroxim may interfere with the results of some laboratory tests done on blood (used in the diagnosis of autoimmune diseases and pregnancy etc.) and urine (to check urine sugar levels). If you or your child have a blood or urine test done whilst you are taking or giving **Ceroxim**, make sure that your doctor or nurse knows about your medicine, **Ceroxim**.

Taking or giving Ceroxim with food and drink

Ceroxim should be taken or given half an hour after food for the best possible absorption.

Pregnancy and Breastfeeding

Safety and effectiveness of **Ceroxim** has not been evaluated in pregnant and nursing mothers.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional advice before taking **Ceroxim**.

Driving and using machinery

Ceroxim may make you dizzy and have other side effects that make you less alert. Do not drive or use machines if you do not feel well.

Important information about some of the ingredients of Ceroxim Tablets

Ceroxim Tablets contain small amounts of some inactive ingredients as listed below:

Sucrose: If you or your child have been told by your doctor that you have intolerance to some sugars or you suffer from the disease known as diabetes mellitus, contact your doctor before taking or giving

Ceroxim Tablets.

Important information about some of the ingredients of **Ceroxim / Ceroxim Forte Suspension**

Ceroxim / Ceroxim Forte Suspension contain small amounts of some inactive ingredients as listed below:

- Sucrose: If you have or your child been told by your doctor that you have intolerance to some sugars or you suffer from the disease known as diabetes mellitus, contact your doctor before taking or giving **Ceroxim / Ceroxim Forte Suspension**.
- Mannitol: It might have a mild laxative effect.
- Aspartame: It is a source of phenylalanine. This may be harmful for people with phenylketonuria.

Taking other medicines with Ceroxim

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines).

Tell your doctor if you or your child are also taking:

- probenecid - this may increase the levels of **Ceroxim** in the blood.
- furosemide - this may cause kidney damage.
- aminoglycoside antibiotics (such as amikacin, gentamicin, kanamycin, neomycin, tobramycin) - this may also cause kidney damage.
- contraceptive pill - **Ceroxim** may reduce the effectiveness of the contraceptive pill.

4. HOW TO TAKE OR GIVE CEROXIM

Do not share medicines prescribed for you with any other person.

Always take or give **Ceroxim** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The doctor will determine the dose and duration of treatment depending on the type and severity of the infection.

Ceroxim has not been studied in children less than 3 months of age.

Ceroxim should be taken in two daily doses.

Because of the bitter taste of cefuroxime axetil, the tablets should not be crushed.

Ceroxim should be taken or given half an hour after food for the best absorption.

Duration of treatment

The usual course of treatment is 7 days, ranging from 5 to 10 days.

If you take or give more Ceroxim than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre. If you have taken or given more **Ceroxim** than you should have, then you or your child may experience fits.

If you forget to take or give Ceroxim

If you forget to take or give a dose, take or give it as soon as you remember, unless it is almost time for your next dose. Do not take or give a double dose to make up for forgotten individual doses. If you miss several doses, contact your doctor.

Effects when treatment with Ceroxim is stopped

It is important to take or give the full course of **Ceroxim**. Never stop taking or giving **Ceroxim** unless on your doctor's advice. If you have the impression that the effect of **Ceroxim** is too strong or too weak, talk to your doctor or pharmacist. If you have any further questions on the use of **Ceroxim**, ask your doctor or pharmacist.

5. POSSIBLE SIDE EFFECTS

Ceroxim can have side effects.

Not all side effects reported for **Ceroxim** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **Ceroxim**, please consult your doctor, pharmacist or other healthcare professional for advice.

The following side effects have been reported:

Side effects indicating need for urgent medical attention:

If any of the following happen, stop taking or giving Ceroxim and tell your doctor immediately or go to the casualty department at your nearest hospital.

- Hypersensitivity reactions (An excessive response by the body to a foreign substance) such as; skin rashes, hives, itching and bronchospasm (tight chest). Swelling of the mouth, lips or throat. Severe skin reactions such as blisters, sores or ulceration.
- Pseudomembranous colitis (stomach cramps or pain, severe watery diarrhoea which may also be bloody and fever).

These are all **very serious** side effects. If you or your child have them you may have had a **serious allergic reaction** or other type of reaction to **Ceroxim**. You or your child may need medical attention or hospitalisation immediately.

Side effects indicating medical attention only if they continue or are bothersome:

Frequent:

- Nausea (Uncomfortable sensation in the stomach along with an urge to vomit), stomach cramps and diarrhoea (loose or watery stools), and headache.
- Fungal infections in the mouth or vagina (Candidiasis).

Less frequent:

- Vomiting

- Skin rashes
- Severe diarrhoea
- Skin reactions (including severe)
- Fever
- Yellowing of the whites of the eyes or skin
- Inflammation of the liver (hepatitis)

Side effects that may show up in blood tests:

- An increase in a type of white blood cell (eosinophilia)
- An increase in liver enzymes
- A decrease in the number of blood platelets (cells that help the blood clot)
- A decrease in the number of white blood cells
- Red blood cells destroyed too quickly (haemolytic anaemia)
- A positive Coomb's test.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF CEROXIM

Keep all medicines out of the reach and sight of children.

Ceroxim 250 / 500 Tablets is stored at or below 25 °C.

The unconstituted suspension is stored at or below 25 °C, protected from moisture.

Keep the container tightly closed.

The constituted **Ceroxim / Ceroxim Forte Suspension** is stored in a refrigerator at 2 °C – 8 °C.

Do not take **Ceroxim** after the expiry date stated on the pack. The expiry date refers to the last day of that month. In order to protect from moisture, do not store in the bathroom.

Return all unused medicine to your pharmacist. Do not be dispose of unused medicine in drains or sewerage systems (e.g. toilets). These measures will help to protect the environment.

7. PRESENTATION OF CEROXIM

Ceroxim 250 / 500 Tablets: Cartons containing PVC/Aclar Blister strips of 10 or 5x10 tablets.

Ceroxim / Ceroxim Forte Suspension is packed in 50 ml and 100 ml HDPE bottle packs that comprise of natural translucent HDPE bottles with Child resistant closure caps. Each packet also contains a measuring cup with graduated markings. Bottles are labelled and packed in cartons.

8. IDENTIFICATION OF CEROXIM

Ceroxim 250 Tablets: White coloured, uncoated caplets, engraved with `RX751` on one side and plain on the other.

Ceroxim 500 Tablets: White coloured, uncoated caplets, engraved with `RX752` on one side and plain on the other.

Ceroxim and Ceroxim Forte Suspension: White to cream-colored granular powder forming white to cream colored suspension on constitution with water. The resulting suspension has a sweet taste and fruity flavor.

9. REGISTRATION NUMBERS

Ceroxim 250 Tablets: 34/20.1.1/0349

Ceroxim 500 Tablets: 34/20.1.1/0350

Ceroxim Suspension: 45/20.1.1/0965

Ceroxim Forte Suspension: 45/20.1.1/0966

10. NAME AND ADDRESS OF REGISTRATION HOLDER

RANBAXY PHARMACEUTICALS (PTY) LTD

14 Lautre Road, Stormill, Ext.1,

Roodepoort, 1724

South Africa

11. DATE OF PUBLICATION

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Ceroxim® 250 mg Tablets

Namibia: NS2 Reg.No.: 05/20.1.1/0191

Botswana: S2 Reg.No.: BOT 0801204

Ceroxim® 500 mg Tablets

Namibia: NS2 Reg.No.: 05/20.1.1/0192

Botswana: S2 Reg.No.: BOT 0801205