PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CEROXIM 250 TABLETS

Sugar free

CEROXIM 500 TABLETS

Sugar free

CEROXIM SUSPENSION

Contains sugar: Sucrose 2,8 g and mannitol 1 g

Contains sweetener: Aspartame 8 mg

CEROXIM FORTE SUSPENSION

Contains sugar: Sucrose 2,5 g and mannitol 1 g

Contains sweetener: Aspartame 8 mg

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, pharmacist, nurse or other healthcare provider.
- 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.

What is in this leaflet

1. What CEROXIM is and what it 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.

2. What you need to know 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 in section 6).
- 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.
- Pregnancy and breastfeeding (see **Pregnancy and breastfeeding**).

Warnings and precautions

Take special care with CEROXIM 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.
- You have chest pains related to reduced blood flow to the heart caused by an allergic reaction (Kounis syndrome)

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 (*pseudomembranous 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) called the *Coombs* test. 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.

Other medicines and CEROXIM

Always tell your healthcare provider if you are taking any other medicine. (This includes all 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.

CEROXIM with food or drink

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please

consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Pregnancy:

Safety and effectiveness of CEROXIM has not been evaluated in pregnant women.

Breastfeeding:

Safety and effectiveness of CEROXIM has not been evaluated in nursing mothers.

Driving and using machines

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.

CEROXIM SUSPENSION AND CEROXIM SUSPENSION FORTE 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.

Mannitol

May have a mild laxative effect.

Aspartame

This medicine contains 8 mg/5 mL. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. 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 or pharmacist has told you. 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.

If you have the impression that the effect of CEROXIM is too strong or too weak, talk to your

doctor or pharmacist.

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 over dosage, 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.

If you stop taking CEROXIM

It is important to take or give the full course of CEROXIM. Never stop taking or giving CEROXIM unless on your doctor’s advice.

4. 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 healthcare provider for advice.

The following side effects have been reported:

If any of the following happens, stop taking 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).
- Jarisch-Herxheimer reaction. Some patients may get a high temperature (fever), chills, headache, muscle pain and skin rash while being treated with CEROXIM
- Chest pains related to reduced blood flow to the heart caused by an allergic reaction (Kounis syndrome)
- Itchy rash with small blisters arranged in rings, which can come up all over the body and limbs (linear IgA disease)

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- 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).
- headache
- dizziness

Less frequent side effects:

- 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.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc-org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CEROXIM.

5. How to store CEROXIM

Store all medicines out of reach of children.

CEROXIM 250/500 Tablets: store 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 dispose of unused medicine in drains or sewerage systems e.g. toilets.

6. Contents of the pack and other information

What CEROXIM contains

The active substance is cefuroxime.

Each CEROXIM 250 Tablet contains cefuroxime axetil equivalent to cefuroxime 250 mg

Each CEROXIM 500 Tablet contains cefuroxime axetil equivalent to cefuroxime 500 mg

The other ingredients in CEROXIM Tablets are: colloidal anhydrous silica (Aerosil-200), croscarmellose sodium, microcrystalline cellulose, purified water, sodium lauryl sulphate, hydrogenated vegetable oil, hypromellose, titanium dioxide, macrogol and talc.

CEROXIM Suspension

Each 5 mL of constituted CEROXIM SUSPENSION contains:

Cefuroxime axetil equivalent to cefuroxime 125 mg

CEROXIM Forte Suspension

Each 5 mL of constituted CEROXIM FORTE suspension contains:

Cefuroxime axetil equivalent to cefuroxime 250 mg

The other ingredients in CEROXIM/ CEROXIM FORTE SUSPENSION are aspartame, flavour peppermint, flavour tutti fruti, mannitol, mono sodium citrate, silica colloidal hydrated, sodium chloride, sodium benzoate 0,2 % m/v (preservative), sucrose and xanthan gum.

What CEROXIM looks like and contents of the pack

CEROXIM 250 Tablets: White to off white film coated modified capsule shaped tablets debossed with `250' on one side and plain on the other.

CEROXIM 500 Tablets: White to off white film coated modified capsule shaped tablets debossed with `500' on one side and plain on the other.

CEROXIM Suspension 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 flavour.

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

CEROXIM Suspension / 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.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD

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South Africa

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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

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

Ceroxim® Suspension

Namibia: NS2 Reg.No.: 18/20.1.1/0063

Ceroxim® Forte Suspension

Namibia: NS2 Reg.No.: 18/20.1.1/0064