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

2. What you need to know before you take CEROXIM

3. How to take CEROXIM

4. Possible side effects

5. How to store CEROXIM

6. Contents of the pack and other information

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.

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

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.

Suspected adverse reactions can also be reported directly to the Holder of certificate of registration via email or telephonically: pharmacovigilance.africasme@sunpharma.com or tel:+27 (0) 12 643 2000

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

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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

PASIËNTINLIGTINGSTUK

SKEDULINGSTATUS: S4

CEROXIM 250 TABLETS

Suikervry

CEROXIM 500 TABLETS

Suikervry

CEROXIM SUSPENSION

Bevat suiker: Sukrose 2,8 g en mannitol 1 g

Bevat versoeter: Aspartaam 8 mg

CEROXIM FORTE SUSPENSION

Bevat suiker: Sukrose 2,5 g en mannitol 1 g

Bevat versoeter: Aspartaam 8 mg

Lees die hele inligtingstuk noukeurig deur voordat jy begin om CEROXIM te gee of te neem

- Hou hierdie inligtingstuk. Dit mag vir jou nodig wees om dit weer te lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer as jy verdere vrae het.
- CEROXIM is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met ander persone deel nie. Dit kan skadelik vir hulle wees, selfs as hulle simptome dieselfde as joune is.

Wat is in hierdie inligtingstuk

1. Wat CEROXIM is en waarvoor dit gebruik word

2. Wat jy moet weet voordat jy CEROXIM neem/gee

3. Hoe om CEROXIM te neem/gee

4. Moontlike newe-effekte

5. Hoe om CEROXIM te bewaar

6. Inhoud van die verpakking en ander inligting

1. Wat CEROXIM is en waarvoor dit gebruik word

CEROXIM behoort aan 'n groep medisyne bekend as antibiotika wat die liggaam help om infeksies te beveg deur sekere bakterieë wat infeksie veroorsaak, dood te maak.

CEROXIM word gebruik vir die behandeling van verskeie bakteriële infeksies.

2. Wat jy moet weet voordat jy CEROXIM neem/gee

Moenie CEROXIM neem/gee as:

- jy of jou kind hipersensitief (allergies) is vir kefuroksiemaksetiel, ander kefalosporien-antibiotika of enige van die ander bestanddele van CEROXIM nie (gelys in afdeling 6).
- jy of jou kind voorheen 'n allergiese reaksie gehad het teen penisillien-antibiotika (soos piperasillien, tikarsillien, ampisillien, amoksisillien, oksasillien, kloksasillien, flukloksasillien, nafsillien ens.); jy mag ook allergies wees vir CEROXIM. Jy moet noukeurig gemonitor word terwyl jy CEROXIM neem.
- Swangerskap en borsvoeding (sien **Swangerskap en borsvoeding**).

Waarskuwings en voorsorgmaatreëls

Tref spesiale voorsorg met **CEROXIM** as:

Jy of jou kind 'n geskiedenis van gastro-intestinale (maag-ingewande) toestande het, veral ulseratiewe kolitis (verswering van die kolon), pseudomembraneuse ('vals-membraan') kolitis of enteritis (onsteking van die ingewande)

Nierinkorting – 'n kleiner dosis mag nodig wees

Porfirie – veiligheid is nog nie geëvalueer nie.

Jy het borspyn wat verband hou met verminderde bloedvloei na di hart, wat deur 'n allergiese reaksie veroorsaak word (Kounis-sindroom)

Lig asseblief jou dokter in voordat CEROXIM geneem of gegee word, selfs as hierdie stellings op enige tyd in die verlede op jou van toepassing was.

As jy of jou kind enige simptome het soos allergiese reaksies, swaminfeksies in die mond (mondsproei) of vagina (vaginitis) wat veroorsaak is deur 'n oorgroei van gis (*Candida*), maagkrampe, abdominale teerheid,

erge en waterige diaree (*pseudomembraneuse kolitis*) terwyl jy CEROXIM neem of gee. Staak die neem of gee van CEROXIM en kontak jou dokter of apteker onmiddellik as hierdie simptome voorkom.

Laboratoriumtoetse

CEROXIM kan inmeng met die uitslag van sommige laboratoriumtoetse wat op bloed gedoen word (gebruik in die diagnose van outoimmuunsiektes en swangerskap ens.) en urine (om bloedsuikervlakke te kontroleer) wat die *Coombs*- toets genoem word. As jy of jou kind ‘n bloed- of urine-toets moet laat doen terwyl CEROXIM geneem of gegee word, moet jy seker maak dat jou dokter of verpleegkundige bewus is van jou medisyne, CEROXIM.

Ander medisyne en CEROXIM

Lig jou gesondheidsorgverskaffer altyd in as jy ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in).

Lig jou dokter in as jy of jou kind ook die volgende neem:

- probenesied – dit kan die vlakke van CEROXIM in die bloed verhoog.
- furosemied – dit kan nierskade veroorsaak.
- aminoglikosied-antibiotika (soos amikasien, gentamisien, kanamisien, neomisien, tobramisien) – dit kan ook nierskade veroorsaak.
- voorbehoedpil - CEROXIM kan die doeltreffendheid van die voorbehoedpil verminder.

CEROXIM saam met voedsel of drinkgoed

CEROXIM moet ‘n halfuur na voedsel geneem of gegee word vir die beste moontlike absorpsie.

Swangerskap en borsvoeding

Indien jy swanger is of borsvoed, dink dat jy swanger mag wees of as jy beplan om ‘n baba te hê, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg vir advies voordat jy hierdie medisyne neem.

Swangerskap:

Veiligheid en doeltreffendheid van CEROXIM is nie in swanger vroue geëvalueer nie.

Borsvoeding:

Veiligheid en doeltreffendheid van CEROXIM is nie in borsvoedende moeders geëvalueer nie.

Bestuur van voertuie en gebruik van masjinerie

CEROXIM kan jou duiselig maak en ander newe-effekte hê wat jou minder waaksaam kan maak. Moenie voertuie bestuur of masjinerie gebruik as jy nie goed voel nie.

CEROXIM SUSPENSION EN CEROXIMSUSPENSION FORTE bevat sukrose

As jy deur jou dokter ingelig is dat jy 'n onverdraagsaamheid teenoor sommige suikers het, moet jy jou dokter kontak voordat jy hierdie medisyne gebruik.

Mannitol

Kan 'n ligte lakserende effek hê.

Aspartaam

Hierdie medisyne bevat 8 mg/5 mL. Aspartaam is 'n bron van fenielalanien. Dit kan skadelik vir jou wees as jy fenielketonurie (FKU) het, 'n seldsame genetiese versteuring waarin die fenielalanien opbou omdat die liggaam dit nie behoorlik kan verwyder nie.

3. Hoe om CEROXIM te neem of te gee

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem of gee CEROXIM altyd presies soos wat jou dokter of apteker jou ingelig het. Kontroleer met jou dokter of apteker as jy onseker is.

Die dokter sal die dosis en duur van behandeling bepaal afhangende van die tipe en ernstigheid van die infeksie.

Praat met jou dokter of apteker as jy onder die indruk is dat die effek van CEROXIM te sterk of te swak is.

CEROXIM is nie in kinders onder die ouderdom van 3 maande bestudeer nie.

CEROXIM moet in twee daaglikse dosisse geneem word.

As gevolg van die bitter smaak van kefuroksiemaksetiel, moet die tablette nie fyngemaak word nie.

CEROXIM moet 'n halfuur na voedsel geneem of gegee word vir die beste absorpsie.

Duur van behandeling

Die normale behandelingskursus is 7 dae, wissel van 5 tot 10 dae.

As jy meer CEROXIM geneem of gegee het as wat jy behoort te neem of te gee

In die geval van oordosering, kontak jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. As jy meer CEROXIM geneem of gegee het as wat jy behoort te neem of te gee, kan jy of jou kind konvulsies ervaar.

As jy vergeet het om CEROXIM te neem of te gee

As jy vergeet het om ‘n dosis te neem of te gee, neem of gee dit so gou as wat jy onthou, tensy dit amper tyd is vir jou volgende dosis. Moenie ‘n dubbele dosis neem of gee om te vergoed vir die individuele dosisse wat jy vergeet het nie. Kontak jou dokter as jy verskeie dosisse oorgeslaan het.

As jy ophou om CEROXIM te neem/gee

Dit is belangrik om die volledige kursus van CEROXIM te neem/gee. Moet nooit ophou om CEROXIM te neem of te gee nie, tensy op jou dokter se advies.

4. Moontlike newe-effekte

CEROXIM kan newe-effekte hê.

Nie alle newe-effekte wat vir CEROXIM aangemeld is, is in hierdie inligtingstuk ingesluit nie. Indien jou algemene gesondheid versleg, of as jy enige ongewenste effekte ervaar terwyl jy CEROXIM neem, moet jy asseblief jou gesondheidsorgverskaffer raadpleeg vir advies.

Die volgende newe-effekte is aangemeld:

Indien enige van die volgende gebeur, staak die gebruik van CEROXIM en lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal:

- Hipersensitiwiteitsreaksies (‘n buitensporige respons van die liggaam teen ‘n vreemde bestanddeel) soos; veluitslag, galbulte, gejeuk en brongospasma (toe bors). Swelling van die mond, lippe of keel. Erge velreaksies soos blasievorming, sere of verswering.
- Pseudomembraneuse kolitis (maagkrampe of pyn, erge waterige diaree wat ook bloederig kan wees en koors).

- Jarisch-Herxheimer-reaksie. Sommige pasiënte kan ‘n hoë koors ontwikkel (koors), koue koors, hoofpyn, spierpyn en veluitslag terwyl hulle behandel word met **CEROXIM**.
- Borspyne wat verband hou met verminderde bloedvloei na die hart wat veroorsaak word deur ,n allergiese reaksie (Kounis-sindroom)
- Jeukerige uitslag met klein blasé wat on ringegerangskik is, wat oral in die liggaam en ledemate kan opkom (lineêre IgA-siekte)

Hierdie is almal baie ernstige newe-effekte. As jy of jou kind hierdie ervaar, mag julle ‘n ernstige reaksie of ander tipe reaksie teen CEROXIM gehad het. Jy of jou kind mag onmiddellike mediese sorg of hospitalisasie benodig.

Lig jou dokter in as jy enige van die volgende opmerk:

Algemene newe-effekte:

- naarheid (ongemaklike gevoel op die maag saam met ‘n drang om te braak), maagkrampe en diaree (los of waterige stoelgange), en hoofpyn.
- swaminfeksies in die mond of vagina (kandidiase).
- hoofpyn
- duiseligheid

Minder algemene newe-effekte:

- braking
- veluitslae
- erge diaree
- velreaksie (insluitend ernstig)
- koors
- vergeling van die wit van die oë of vel
- ontsteking van die lewer (hepatitis)

Newe-effekte wat mag uitkom in bloedtoetse:

- ‘n Verhoging in ‘n tipe witbloedsel (eosinofilie)
- ‘n Toename in lewerensieme

- ‘n Afname in die aantal bloedplaatjies (selle wat help dat die bloed stol)
- ‘n Afname in die aantal witbloedselle
- Rooibloedselle wat te vinnig vernietig word (hemolitiese anemie)
- ‘n Positiewe Coombs se toets.

Lig jou dokter of apteker in as jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk opgeneem is nie.

Aanmelding van newe-effekte

Praat met jou dokter, apteker of verpleegkundige as jy newe-effekte kry. Jy kan ook newe-effekte by SAHPRA aanmeld *via* die Med Safety APP (Medsafety X SAHPRA) en e-verslaggewing platform (who-umc.org) gevind op SAHPRA webwerf. Deur newe-effekte aan te meld, kan jy help om inligting te verskaf oor die veiligheid van CEROXIM.

As nadelige reaksjes vermoed word kan die ook direk aan die Houer van sertifikaat van registrasie per e-pos of telefonies gerapporteer word: pharmacovigilance.africasme@sunpharma.com of tel:+27(0) 12 643 2000

5. Hoe om CEROXIM te bewaar

Bewaar alle medisyne buite die bereik van kinders.

CEROXIM 250/500 Tablets: bewaar by of onder 25 °C.

Bewaar die suspensie wat nog nie hersaamgestel is nie by of onder 25 °C, beskerm teen vog.

Hou die houer dig toe.

Die hersaamgestelde CEROXIM / CEROXIM Forte Suspension word in ‘n yskas teen 2 °C – 8 °C bewaar.

Moenie CEROXIM ná die vervaldatum soos op die verpakking aangedui, gebruik nie. Die vervaldatum verwys na die laaste dag van daardie maand. Moenie in die badkamer bewaar nie om dit teen vog te beskerm.

Bring alle ongebruikte medisyne terug na jou apteker toe.

Moenie van ongebruikte medisyne in dreinerings- of rioleringstelsels (bv. toilette) ontslae raak nie.

6. Inhoud van die verpakking en ander inligting

Wat CEROXIM bevat

Die aktiewe bestanddeel is kefuroksiem.

Elke CEROXIM 250 Tablet bevat kefuroksiemaksetiel gelykstaande aan 250 mg kefuroksiem.

Elke CEROXIM 500 Tablet bevat kefuroksiemaksetiel gelykstaande aan 500 mg kefuroksiem.

Die ander bestanddele in CEROXIM Tablets is: kolloïdale anhidriese silika (Aerosil-200), natriumkroskarmellose, mikrokristallyne sellulose, natriumlourielsulfaat, gehidrogeneerde groente-olie, tilaandioksied, makrogol, talk, hipromellose

CEROXIM Suspension

Elke 5 mL van die hersaamgestelde CEROXIM SUSPENSION bevat: kefuroksiemaksetiel gelykstaande aan 125 mg kefuroksiem

CEROXIM Forte Suspension

Elke 5 mL van die hersaamgestelde CEROXIM FORTE suspension bevat: kefuroksiemaksetiel gelykstaande aan 250 mg kefuroksiem

Die ander bestanddele in CEROXIM/ CEROXIM FORTE SUSPENSION is aspartaam, pepermentgeur, tutti fruti-geur, mannitol, mononatriumsitraat, gehidreerde kolloïdale silika, natriumchloried, natriumbensoaat 0,2 % m/v (preserveermiddel), sukrose en xantangom.

Hoe CEROXIM lyk en inhoud van die verpakking

CEROXIM 250 Tablets: Wit tot naaswit filmbedekte gemodifiseerde kapsulevormige tablette met `250' aan die een kant en glad aan die ander kant.

CEROXIM 500 Tablets: Wit tot naaswit filmbedekte gemodifiseerde kapsulevormige tablette met `500' aan die een kant en glad aan die ander kant.

CEROXIM en CEROXIM Forte Suspension: Wit tot roomkleurige granulêre poeier wat 'n wit tot roomkleurige suspensie vorm wanneer dit met water hersaamgestel word. Die gevolglike suspensie het 'n soet smaak en vrugtige geur.

CEROXIM 250 / 500 Tablets: Kartonne bevat PVC/Aclar stulpstroke van 10 of 5x10 tablette.

CEROXIM / CEROXIM Forte Suspensions word verpak in 50 mL en 100 mL HDPE-bottelverpakkings wat bestaan uit natuurlike deurskynende HDPE-bottels met kinderveilige skroefdoppe. Elke pakkie bevat ook 'n maatkoppie met gegradeerde merke. Bottels word geëtiketteer en in kartonne verpak.

Houer van die Registrasiesertifikaat

RANBAXY PHARMACEUTICALS (PTY) LTD

'n Sun Pharma maatskappy

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Hierdie inligtingstuk was laas hersien in

26 Januarie 2023.

Registrasienommers

CEROXIM 250 Tablets: 34/20.1.1/0349

CEROXIM 500 Tablets: 34/20.1.1/0350

CEROXIM Suspension: 45/20.1.1/0965

CEROXIM Suspension: 45/20.1.1/0966

Ceroxim® 250 mg Tablets

Namibië: NS2 Reg.Nr.: 05/20.1.1/0191

Botswana: S2 Reg.Nr.: BOT 0801204

Ceroxim® 500 mg Tablets

Namibië: NS2 Reg.Nr.: 05/20.1.1/0192

Botswana: S2 Reg.Nr.: BOT 0801205