SCHEDULING STATUS: S4

Cepodem 100 Tablets

Cefpodoxime proxetil 100 mg /tablet

Contains sugar:

Lactose anhydrous 10,0 mg /film-coated tablet

Cepodem 200 Tablets

Cefpodoxime proxetil 200 mg /tablet

Contains sugar:

Lactose anhydrous 20,0 mg /film-coated tablet

Cepodem Suspension 40 mg/5 ml (Powder for Oral Suspension)

Cefpodoxime proxetil 40 mg/ 5ml suspension

Contains sugar:

Sucrose 2,7 g & lactose anhydrous 7, 23 mg/ 5 ml suspension

Read all of this leaflet carefully before you start taking Cepodem

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor,pharmacist nurse or other health care provider.
- Cepodem 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 CEPODEM is and what it is used for

2. What you need to know before you take CEPODEM

3. How to take CEPODEM

4. Possible side effects

5. How to store CEPODEM

6. Contents of the pack and other information

1. What CEPODEM is and what it is used for

Cepodem contains a medicine called cefpodoxime proxetil. This belongs to a group of antibiotics called 'cephalosporins'. Antibiotics help the body fight infections by destroying certain bacteria that cause infection.

In adults:

Cepodem Tablets are used to treat infections caused by bacteria. These include:

- nose & sinuses infections (such as sinusitis)
- throat infections (such as tonsillitis, pharyngitis)
- chest and lungs infections (such as bronchitis, pneumonia)

In children:

Cepodem Suspension 40 mg/5 ml is used to treat infections caused by bacteria . These include:

- ear infections (otitis media)
- nose & sinuses infections (such as sinusitis)
- throat infections (such as tonsillitis, pharyngitis)
- chest and lungs infections (such as bronchitis, pneumonia)

2. What you need to know before you give or take CEPODEM

Do not take or give Cepodem if:

- You or your child is (hypersensitive) to cefpodoxime or to any of the cephalosporin group of antibiotics, any other antibiotics including penicillin or to any of the other ingredients of Cepodem (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat and tongue.
- You are pregnant, you think may be pregnant or currently breastfeeding.
- Cepodem should not be used in children below 1 year of age.

Do not use this medicine if any of the above applies to you or your child. If you are not sure, talk to your child's doctor or your pharmacist before giving Cepodem.

Warnings and precautions

Take special care with Cepodem and talk with your doctor if:

- You/your child have previously had an allergic (hypersensitive) reaction to penicillin and other beta-lactam antibiotics (such as piperacillin, ticarcillin, ampicillin, amoxicillin, oxacillin, cloxacillin, flucloxacillin, nafcillin etc.); you may also be allergic to cefpodoxime proxetil, you should be strictly monitored while taking this medicine.
- You/your child suffer from kidney problems.
- You/your child develop severe and persistent diarrhoea which may contain blood or mucous along with stomach cramps and fever (pseudomembranous colitis). Immediately stop taking or giving Cepodem and contact your doctor.

If you are not sure if any of the above applies, talk to doctor before taking Cepodem.

The doctor will tell you whether it is safe for you/your child to start taking this medicine.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Other medicines and CEPODEM

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the medicines listed below, as special care should then be taken:

- antacids (used to treat indigestion)
- medicines for treating ulcers (such as ranitidine or cimetidine)
- probenecid (a medicine to stop kidney damage)

Take antacids and medicines for ulcers 2-3 hours after Cepodem.

Cepodem can enhance the anti-clotting effect of warfarin and reduce the contraceptive effect of oestrogens.

Tests

This medicine may interfere with the results of some laboratory tests done on blood (Coombs tests). If a blood test is done while taking Cepodem, make sure that doctor or nurse knows about your medicine.

A false positive reaction for glucose in the urine may occur with certain tests such as Benedict's or Fehling's solution or with copper sulphate test tablets.

CEPODEM with food and drink

Cepodem should be taken with meals.

Pregnancy and breastfeeding

The safety of Cepodem during pregnancy and breastfeeding has not been established. It is recommended that women taking Cepodem do not breastfeed their infants.

If you are pregnant or breastfeeding your baby , think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

Dizziness may occur, which should be taken into account when driving a vehicle or operating machines. Make sure you know how you react to Cepodem before you drive, use machines, or engage in any other activity that could be dangerous if you are not alert.

Cepodem tablets contains lactose.

Cepodem suspension 40 mg/5 ml contains sucrose and lactose.

If you have been told by your doctor that you/your child have an intolerance to some sugars, contact your doctor before taking/giving this medicine.

3. HOW TO TAKE OR GIVE CEPODEM

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

Always take Cepodem exactly as your doctor has instructed you. Do not take more than the doctor told you to. Check the label carefully for how much to take and how often to take You should check with your doctor or pharmacist if you are not sure.

Use in adults

The dosage of **Cepodem Tablets** depends on the condition being treated.

- ***For throat, chest and lungs infections (tonsillitis, pharyngitis, acute bronchitis)***

  One **Cepodem 100 Tablet** every 12 hours with meals (200 mg/day). In certain type of infections (streptococcal infections) the dose would be given for at least 10 days by your doctor.

- ***For sinus, chest and lung infections (acute sinusitis, bronchitis and pneumonia)***

  One **Cepodem 200 Tablet** or two **Cepodem 100 Tablets** every 12 hours with meals (400 mg/day).

Patients with kidney problems

Your doctor will decide your dose based on your kidney function.

Elderly patients

Where renal function is normal, it is not necessary to adjust the dose.

Use in children

Cepodem suspension is available for children.

- The constituted product contains cefpodoxime 8 mg/ml.
- An average dose of 8 mg/kg/day administered in two doses at 12 hourly intervals with meals.

Cepodem Suspension 40 mg/5 ml is not indicated for use in children less than one year of age.

Directions for reconstitution of suspension: Shake the bottle to loosen the granules. Add 33 ml and 66 ml water for 50 ml and 100 ml packs respectively in two divided portions to the dry mixture in the bottle. Shake well after each addition.

Always take **Cepodem** exactly as your doctor has told you.

You should check with doctor or pharmacist if you are not sure how you should take your medicine or give medicine to your child.

If you take/give more CEPODEM than you should

- In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

- Show them the pack of Cepodem (tablets or suspension).

If you forget to take/give CEPODEM:

- If you miss a dose, take/give the missed dose as soon as possible, and then continue with the normal dose on the regular schedule as prescribed by the doctor.
- Do not take/give a double dose to make up for a forgotten dose.

If you stop taking Cepodem

- Do not stop or change the daily dose of Cepodem without first consulting with the doctor.
- Cepodem should always be taken every day to help control the infection, no matter how much better you/your child feel.
- Using **Cepodem** as recommended should give the best chance of delaying the development of resistance to the product.
- If a side effect is preventing you/your child from taking **Cepodem** as directed tell the doctor right away.
- Continue to take this medicine or give this medicine to your child until your doctor tells you otherwise.

If you have any further questions on the use of this product, ask the doctor or pharmacist.

4 Possible side effects

Cepodem can have side effects.

Not all side effects reported for Cepodem are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Cepodem, please consult your health care provider for advice.

If any of the following happens, stop taking/giving Cepodem and tell your doctor immediately or go/take your child to the casualty department at your nearest hospital.

- Fever, swelling of the face, lips, tongue, throat, hands/feet, skin rash, enlargement of the lymph nodes, joint pain (serum sickness) or breathing difficulties.
- Flu-like symptoms followed by blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. This may be a severe skin allergy, called ‘Stevens-Johnson syndrome’

- Severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles. This may be a serious condition called 'Toxic epidermal necrolysis'
- Painful or itchy lesions that have a pink-red centre surrounded by a pale ring border and outer pink-red-ring. The more severe form can affect the mouth, genitals and eyes and can be life-threatening. This may be a serious skin allergy called 'Erythema multiforme'

These are very serious side effects. If you/your child have them you/your child may have had a serious reaction to Cepodem. You/your child may need urgent medical attention or hospitalization. Remember to take any medicine that is left so the doctor knows what you/your child have taken.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Skin rash or lesions with a pink or red ring and a pale centre which may be itchy or filled with fluid (bullous eruptions).
- Rash, redness and swelling of skin, itching, hives, pimples (urticaria, purpura, pruritis).
- Numbness or tingling feelings (paresthesia)
- Yellowing of skin, eyes or mouth and feeling tired. You may also be pale than normal (reduction in haemoglobin)
- Severe and persistent diarrhoea which may contain blood or mucous along with stomach cramps and fever (pseudomenmbraneous colitis).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- feeling sick (nausea), being sick (vomiting), stomach pain or cramps,
- headache
- increased eosinophils (eosinophillia)

Less frequent side effects:

- loose stool (diarrhoea)

- dizziness, ringing in the ears (tinnitus)
- body pain, feeling uneasy (malaise), tired, weak or lack of energy (asthenia)
- superinfection (a second infection which occurs during the course of the existing infection, by other bacteria or organisms resistant to Cepodem), including fungal infections such as oral or vaginal thrush.
- liver injury resulting in abnormal liver function tests (increase in AST, ALT, ALP)
- abnormal kidney function tests (increase in BUN and creatinine)
- increased or decreased platelets (thrombocytosis, thrombocytopenia)
- reduced hemoglobin, white blood cells (agranulocytosis), neutrophils (neutropenia), leukocytes (leucopenia)
- taste disturbances, inflamed and sore mouth, dry mouth.

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 "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Cepodem.

5.How to store CEPODEM

- Store all medicines out of reach of children.
- Store at or below 25 °C,
- Do not use after the expiry date stated on the label/ carton. The expiry date refers to the last day of that month.
- Store in the original package/ container.
- Keep the container in the outer carton.
- Keep the container tightly closed.
- Do not remove the blister strips from the cartons until required for use.
- Protect from light and moisture.
- Do not store in a 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 CEPODEM contains

The active substance is cefpodoxime proxetil. It is available as tablets in strengths of 100 mg and 200 mg and as a 40 mg/5 ml suspension.

The other ingredients in **Cepodem Tablets** are:

Tablet core: carboxymethyl cellulose calcium, hydroxypropylcellulose, lactose anhydrous, magnesium stearate, sodium lauryl sulphate,

Film-coat: Opadry white 03H58987 consisting of hypromellose, titanium dioxide and propylene gylcol

Printing Ink: Opacode-S-1-17823 consisting of shellac glaze, iron oxide black, n-butyl alcohol, propylene glycol.

The other ingredients in **Cepodem suspension** are: carboxymethyl cellulose, carrageenan, , citric acid, colloidal anhydrous silica, croscarmellose sodium, hydroxypropyl cellulose, lactose anhydrous, microcrystalline cellulose sodium, sodium benzoate 0,2 % *m/v* (as preservative), sodium citrate, sucrose ,Flavourant: Flavour Cherry; Flavour Fruit Gum

Colourant: Ferric Oxide Yellow

What CEPODEM looks like and contents of the pack

Cepodem 100 Tablets*:* White coloured, capsule shaped, film coated tablets imprinted with `RX520' on one side in black edible ink.

Cepodem 200 Tablets: White coloured, capsule shaped, film coated tablets imprinted with `RX521' on one side in black edible ink.

Cepodem Suspension 40 mg/5 ml: Off-white to yellow granular powder forming an off-white to yellow suspension on constitution with water. The resulting suspension has a characteristic fruity flavour.

Cepodem 100 Tablets: Aluminium strip pack of 10 tablets.

Cepodem 200 Tablets: Aluminium strip pack of 10 tablets.

Cepodem Suspension 40 mg/5 ml: Natural translucent HDPE bottle pack of 50 ml and 100 ml.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

A Sun Pharma Company

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South Africa

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Cepodem 100 Tablets: 36/20.1.1/0225

Cepodem 200 Tablets: 36/20.1.1/0226

Cepodem Suspension 40 mg/5 ml: 36/20.1.1/0227

Namibia:

Cepodem 100 NS2 07/20.1.1/0024

Cepodem 200 NS2 07/20.1.1/0025

Cepodem Suspension 40 mg/5 ml NS2 07/20.1.1/0026

PASIËNTINLIGTINGSTUK

SKEDULINGSTATUS: S4

Cepodem 100 Tablets

Kefpodoksiemproksetiel 100 mg /tablet

Bevat suiker:

Anhidriese laktose 10,0 mg /filmbedekte tablet

Cepodem 200 Tablets

Kefpodoksiemproksetiel 200 mg /tablet

Bevat suiker:

Anhidriese laktose 20,0 mg /filmbedekte tablet

Cepodem Suspension 40 mg/5 ml (Powder for Oral Suspension)

Kefpodoksiemproksetiel 40 mg/ 5ml suspension

Bevat suiker:

Sukrose 2,7 g & anhidriese laktose 7, 23 mg/ 5 mL suspensie

Lees die hele inligtingstuk noukeurig deur voordat jy begin om Cepodem te neem

- Hou hierdie inligtingstuk. Dit mag vir jou nodig wees om dit weer te lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgvoorsiener as jy verdere vrae het.
- Cepodem 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 is CEPODEM is en waarvoor word dit gebruik

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

3. Hoe om CEPODEM te neem/gee

4. Moontlike newe-effekte

5. Hoe om CEPODEM te bewaar

6. Inhoud van die verpakking en ander inligting

1. Wat is CEPODEM en waarvoor word dit gebruik

Cepodem bevat ‘n medisyne wat kefpodoksiemproksetiel genoem word. Dit behoort aan ‘n groep van antibiotika bekend as ‘kefalosporiene’. Antibiotika help die liggaam om infeksies te beveg deur sekere bakterieë te vernietig wat infeksies veroorsaak.

In volwassenes:

Cepodem Tablets word gebruik om infeksies wat deur bakterieë veroorsaak word, te behandel. Dit sluit in:

- neus- & sinusinfeksies (soos sinusitis)
- keelinfeksies (soos tonsillitis, faringitis)
- bors-en longinfeksies (soos brongitis, longontsteking)

In kinders:

Cepodem Suspension 40 mg/5 mL word gebruik om infeksies wat deur bakterieë veroorsaak word, te behandel. Dit sluit in:

- oorinfeksies (otitis media)
- neus- & sinusinfeksies (soos sinusitis)
- keelinfeksies (soos tonsillitis, faringitis)
- bors- en longinfeksies (soos brongitis, longontsteking)

2. Wat jy moet weet voordat CEPODEM geneem/gegee word

Moenie Cepodem neem/gee as:

- Jy of jou kind allergies (hipersensitief) is teen kefpodoksiem of teen enige van die kefalosporien-groep van antibiotika, enige ander antibiotikum, insluitend penisillien of teen enige van die ander bestanddele van Cepodem (gelys in afdeling 6). Tekens van ‘n allergiese reaksie sluit in: ‘n uitslag, sluk- of asemhalingsprobleme, swelling van die lippe, gesig, keel en tong.
- Jy swanger is, dink dat jy swanger mag wees of tans borsvoed.
- Cepodem moet nie in kinders onder die ouderdom van 1 jaar gebruik word nie.

Moenie hierdie medisyne gebruik as enige van bogenoemde op jou of jou kind van toepassing is nie. As jy nie seker is nie, praat met jou kind se dokter of jou apteker voordat Cepodem gegee word.

Waarskuwings en voorsorgmaatreëls

Tref spesiale voorsorg met Cepodem en praat met jou dokter as:

- Jy/jou kind voorheen 'n allergiese (hipersensitiwiteitsreaksie) reaksie teen penisillien en ander beta-laktaam antibiotika (soos piperasillien, tikarsillien, ampisillien, amoksisillien, oksasillien, kloksasillien, flukloksasillien, nafsillien ens.) gehad het; jy mag ook allergies wees vir kefpodoksiemproksetiel en jy moet noukeurig dopgehou word terwyl jy hierdie medisyne neem.
- Jy/jou kind ly aan nierprobleme.
- Jy/jou kind ernstige en aanhoudende diaree ontwikkel, wat bloed of slym kan bevat, saam met maagkrampe en koors (pseudomembraneuse kolitis). Staak die gebruik of gee van Cepodem onmiddellik en kontak jou dokter.

Praat met jou dokter voordat Cepodem geneem word as enige van bogenoemde van toepassing is.

Die dokter sal jou inlig of dit veilig is vir jou/jou kind om te begin om hierdie medisyne te neem.

Raadpleeg asseblief jou dokter, selfs as hierdie stellings op enige tydstip in die verlede op jou van toepassing was.

Ander medisyne en CEPODEM

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

Lig jou dokter in as jy enige van die medisyne hieronder gelys, gebruik aangesien spesiale sorg toegepas moet word:

- teensuurmiddels (gebruik om slegte spysvertering te behandel)
- medisyne vir die behandeling van maagsere (soos ranitidien of simetidien)
- probenesied ('n medisyne om nierskade te stop)

Neem teensuurmiddels en medisyne vir maagsere 2-3 uur na Cepodem.

Cepodem kan die teen-stollingseffek van warfarien versterk en verminder die kontraseptiewe effek van estrogene.

Toetse

Hierdie medisyne mag inmeng met die resultate van sommige laboratoriumtoetse wat op bloed gedoen word (Coombs toetse). As 'n bloedtoets gedoen word terwyl jy Cepodem gebruik, maak seker dat jou dokter of verpleegster weet van jou medisyne.

'n Vals-positiewe reaksie vir glukose in die urine kan voorkom met sekere toetse soos Benedict of Fehling se oplossing of met kopersulfaat-toetstablette.

CEPODEM saam met voedsel en drinkgoed

Cepodem moet saam met maaltye geneem word.

Swangerskap en borsvoeding

Die veiligheid van Cepodem tydens swangerskap en borsvoeding is nie vasgestel nie. Daar word aanbeveel dat vrouens wat Cepodem neem, nie hulle suigelinge borsvoed nie.

As jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om 'n baba te hê, moet jy asseblief jou dokter, apteker of ander gesondheidsorgvoorsiener raadpleeg vir advies voordat jy hierdie medisyne gebruik.

Bestuur en gebruik van masjinerie

Duiseligheid kan voorkom, wat in aanmerking geneem moet word wanneer 'n voertuig bestuur word of masjinerie hanteer word. Maak seker dat jy weet hoe jy teenoor Cepodem reageer voordat jy bestuur, masjinerie gebruik, of betrokke raak by enige aktiwiteit wat gevaarlik mag wees as jy nie waaksaam is nie.

Cepodem tablette bevat laktose.

Cepodem suspension 40 mg/5 mL bevat sukrose en laktose.

As jy deur jou dokter ingelig is dat jy/jou kind 'n onverdraagsaamheid teenoor sommige suikers het, moet jy jou dokter kontak voordat hierdie medisyne geneem/gegee word.

3. HOE OM CEPODEM TE NEEM OF TE GEE

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

Neem Cepodem altyd presies soos wat jou dokter dit vir jou voorgeskryf het. Moenie meer neem as wat jou dokter voorgeskryf het nie. Bestudeer die etiket noukeurig vir hoeveel en hoe dikwels om die medikasie te neem. Jy moet met jou dokter of apteker bevestig as jy onseker is.

Gebruik in volwassenes

Die dosis van **Cepodem Tablets** hang af van die toestand wat behandel word.

- ***Vir keel-, bors- en longinfeksies (tonsillitis, faringitis, akute brongitis)***

  Een **Cepodem 100 Tablet** elke 12 uur saam met 'n ete (200 mg/dag). In sekere tipes van infeksies (streptokokkale infeksies) sal die dosis vir ten minste 10 dae deur jou dokter voorgeskryf word.

- ***Vir sinus-, bors- en longinfeksies (akute sinusitis, brongitis en longontsteking)***

  Een **Cepodem 200 Tablet** of twee **Cepodem 100 Tablets** elke 12 uur saam met 'n etes (400 mg/dag).

Pasiënte met nierprobleme

Jou dokter sal op jou dosis besluit gebaseer op jou nierfunksie.

Bejaarde pasiënte

Wanneer nierfunksie normaal is, is dit nie nodig om die dosis aan te pas nie.

Gebruik in kinders

Cepodem suspension is beskikbaar vir kinders

Die hersaamgestelde produk bevat kefpodoksiem 8 mg/mL

- 'n Gemiddelde dosis van 8 mg/kg/dag toegedien in twee dosisse teen 12 uur intervalle met etes.

Cepodem Suspension 40 mg/5 ml is nie aangedui vir gebruik in kinders onder die ouderdom van een jaar nie.

Aanwysings vir hersamestelling van die suspensie: Skud die bottel om die granules los te maak. Voeg 33 mL en 66 mL water vir 50 mL en 100 mL verpakkings, respektiewelik, in twee verdeelde porsies by die droë mengsel in die bottel. Skud goed na elke toevoeging.

Neem **Cepodem** altyd presies soos wat jou dokter dit voorgeskryf het.

Jy moet met jou dokter of apteker bevestig as jy nie seker is hoe om jou medisyne te neem of medisyne vir jou kind te gee nie.

As jy meer CEPODEM geneem/gegee het as wat jy behoort te neem/gee

- In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
- Wys die pakkie van Cepodem (tablette of suspensie) aan hulle.

As jy vergeet het om CEPODEM te neem/gee:

- As jy 'n dosis oorgeslaan het, neem/gee die oorgeslaande dosis so gou as moontlik, en gaan dan voort met die normale dosisskedule soos deur jou dokter voorgeskryf is.
- Moenie 'n dubbele dosis neem/gee om te vergoed vir die dosis wat oorgeslaan is nie.

As jy ophou om Cepodem te neem/gee

- Moenie ophou of die daaglikse dosis van Cepodem verander sonder om jou dokter eers te raadpleeg nie.
- Cepodem moet altyd elke dag geneem word om te help om die infeksie te beheer, maak nie saak hoeveel jy/jou kind beter voel nie.
- Gebruik **Cepodem** soos voorgeskryf aangesien dit die beste manier is om die ontwikkeling van weerstand teen die produk te vertraag.
- As 'n newe-effek jou/jou kind verhoed om **Cepodem** soos voorgeskryf te neem, moet jou dokter dadelik daarvan kennis neem.
- Gaan voort om hierdie medisyne te neem of om hierdie medisyne aan jou kind te gee totdat jou dokter jou andersins inlig.

Vra jou dokter of apteker as jy enige verdere vrae het oor die gebruik van hierdie produk.

4 Moontlike newe-effekte

Cepodem **k**an newe-effekte hê.

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

As enige van die volgende gebeur, hou op om Cepodem te neem/te gee en lig jou dokter onmiddellik in of gaan/neem jou kind na die noodgevalle afdeling by jou naaste hospitaal.

- Koors, swelling van die gesig, lippe, tong, keel, hande/voete, veluitslag, vergroting van die limfknope, gewrigspyn (serumsiekte) of asemhalingsprobleme.
- Griepagtige simptome gevolg deur blasievorming of bloeding van die vel rondom die lippe, oë, mond, neus en geslagsdele. Dit kan ‘n ernstige velallergie wees, wat ‘Stevens-Johnson sindroom’ genoem word.
- Ernstige blasie-agtige uitslag waar lae van die vel kan afskilfer om groot areas van rou blootgestelde vel oor die ligaam agter te laat. Ook ‘n algemene onwel-gevoel, koors, koue koors en seer spiere. Dit mag ‘n ernstige toestand wees wat ‘Toksiese epidermale nekrolise’ genoem word.
- Pynlike of jeukende letsels wat ‘n pienk-rooi sentrum het omring deur ‘n dowwe kring rondom en buitenste pienk-rooi kring. Die meer ernstige vorm kan die mond, geslagsdele en oë affekteer en kan lewensbedreigend wees. Dit mag ‘n ernstige velallergie wees wat ‘Veelvuldige eriteem’ genoem word.

Hierdie is baie ernstige newe-effekte. As jy/jou kind dit het, kon jy/jou kind ‘n ernstige reaksie teen Cepodem gehad het. Jy/jou kind mag dringende mediese aandag of hospitalisasie benodig. Onthou om enige medisyne wat oorgebly saam te neem sodat jou dokter kan weet wat jy/jou kind geneem het.

Lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- Veluitslag of letsels met ‘n pienk of rooi kring en ‘n dowwe sentrum wat jeukerig of met vloeistof gevul kan wees (blasie-agtige uitslag).
- Uitslag, rooiheid en swelling van vel, gejeuk, galbulte, puisies (urtikarie, purpura, pruritis).
- Doodse gevoel of tintelende gevoel (parestesie)
- Vergeling van vel, oë of monde n moeë gevoel. Jy kan ook meer bleek as normaal wees (afname in hemoglobien)
- Ernstige en aanhoudende diaree, wat bloed en slym bevat, saam met maagkrampe en koors (pseudomembraneuse kolitis).

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese aandag benodig.

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

Dikwelse newe-effekte:

- mislike gevoel (naarheid), gooi op (braking), maagpyn of krampe,

- hoofpyn
- verhoogde eosinofiele (eosinofilie)

Minder dikwelse newe-effekte:

- los stoelgang (diaree)
- duiseligheid, suising in die ore (tinnitus)
- liggaamspyn, ongemaklike gevoel (malaise), moeg, swak of sonder energie (astenie)
- superinfeksie ('n tweede infeksie wat voorkom tydens die verloop van die bestaande infeksie, deur ander bakterieë of organismes wat weerstandig is teen Cepodem), insluitend fungusinfeksies soos mondelikse of vaginale sproei.
- Lewerbeskadiging wat lei tot abnormale lewerfunksie-toetse (verhoging in AST, ALT, ALP)
- abnormale nierfunksie-toetse (verhoging in BUN en kreatinien)
- verhoogde of verlaagde plaatjies (trombositose, trombositopenie)
- verlaagde hemoglobien, witbloedselle (agranulositose), neutrofiele (neutropenie), leukosiete (leukopenie)
- smaakversteurings, ontsteekte en seer mond, droë mond.

As jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, moet jy asseblief jou dokter of apteker inlig.

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 "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn onder SAHPRA se publikasies beskikbaar is. https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om inligting te verskaf oor die veiligheid van Cepodem.

5. Hoe om CEPODEM te bewaar

- Bewaar alle medisyne buite die bereik van kinders.
- Bewaar by of benede 25 °C,
- Moenie na die vervaldatum soos op die etiket/ karton aangedui, gebruik nie. Die vervaldatum verwys na die laaste dag van daardie maand.
- Bewaar in die oorspronklike verpakking/ houer.

- Hou die houer in die buitenste karton.
- Hou die houer dig toe.
- Moenie die stulpstroke uit die karton verwyder tot benodig vir gebruik nie.
- Beskerm teen lig en vog.
- Moenie in die badkamer bewaar nie.
- 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 CEPODEM bevat

Die aktiewe bestanddeel is kefpodoksiemproksetiel. Dit is beskikbaar as tablette in sterktes van 100 mg en 200 mg en as ‘n 40 mg/5 mL suspensie.

Die ander bestanddele in **Cepodem Tablets** is:

Tabletkern: kalsium-karboksimetielsellulose, hidroksipropielsellulose, anhidriese laktose, magnesiumstearaat, natriumlourielsulfaat

Filmbedekking: Opadry wit 03H58987 bestaande uit hipromellose, titaniumdioksied en propileenglikool

Drukkersink: Opacode-S-1-17823 bestaande uit shellakglans, swart ysteroksied, n-butielalkohol, propileenglikool.

Die ander bestanddele in **Cepodem suspension** is: natriumkarboksimetielsellulose, karrageenan, sitroensuur, anhidriese kolloïdale silika, natriumkroskarmellose, hidroksipropielsellulose, anhidriese laktose, natrium-mikrokristallyne sellulose, natriumbensoaat 0,2 % *m/v* (as preserveermiddel), natriumsitraat, sukrose. Geurmiddel: Kersiegeur; Vrugtegomgeur.

Kleurstof: Geel ysteroksied

Hoe CEPODEM lyk en inhoud van die verpakking

Cepodem 100 Tablets*:* Wit gekleurde, kapsulevormige, filmbedekte tablette gedruk met `RX520' op een kant in swart eetbare ink.

Cepodem 200 Tablets: Wit gekleurde, kapsulevormige, filmbedekte tablette gedruk met RX521' op een kant in swart eetbare ink.

Cepodem Suspension 40 mg/5 ml: Naaswit tot geel granulêre poeier wat 'n naaswit tot geel suspensie vorm na hersamestelling met water. Die hersaamgestelde suspensie het 'n kenmerkende vrugtige geur.

Cepodem 100 Tablets: Aluminiumstulpverpakking van 10 tablette elk.

Cepodem 200 Tablets: Aluminiumstulpverpakking van 10 tablette elk.

Cepodem Suspension 40 mg/5 mL: Natuurlike deursigtige HDPE bottelverpakking van 50 mL en 100 mL.

Houer van die Registrasiesertifikaat

Ranbaxy Pharmaceuticals (Pty) Ltd

'n Sun Pharma maatskappy

Lautreweg 14, Stormill Uitbreiding 1

Roodepoort, 1724

Suid-Afrika

Hierdie inligtingstuk was laas hersien in

September 2022

Registrasienommers

Cepodem 100 Tablets: 36/20.1.1/0225

Cepodem 200 Tablets: 36/20.1.1/0226

Cepodem Suspension 40 mg/5 mL: 36/20.1.1/0227

Namibia:
Cepodem 100 NS2 07/20.1.1/0024
Cepodem 200 NS2 07/20.1.1/0025
Cepodem Suspension 40 mg/5 ml NS2 07/20.1.1/0026