APPROVED PATIENT INFORMATION LEAFLET

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/ 5 mL 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 healthcare 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

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.
- You have chest pains in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)

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.
- Chest pains which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome
- 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'
- Severe skin reactions such as blisters in a circle with central crusting or like a string of pearls (linear IgA disease), sores or ulceration
- 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

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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

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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 Tablets NS2 07/20.1.1/0024

CEPODEM 200 Tablets NS2 07/20.1.1/0025

CEPODEM Suspension 40 mg/5 mL NS2 07/20.1.1/0026

Botswana

CEPODEM 100 Tablets S2 BOT1302376A

CEPODEM 200 Tablets S2 BOT1302376B