PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

CEFPODOXIME 40 mg / 5 ml UNICORN (powder for oral suspension)

Cefpodoxime proxetil

Contains sugar: Sucrose (2464,67 mg / 5 ml)

Contains sweetener: Aspartame (20,00 mg / 5 ml)

Contains preservative: Sodium benzoate (0.2 % *m/v*)

Read all of this leaflet carefully before giving CEFPODOXIME 40 mg / 5 ml UNICORN to your child

- 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.
- **CEFPODOXIME 40 mg / 5 ml UNICORN** has been prescribed for your child and you should not share this medicine with other people. It may harm them, even if their symptoms are the same as the symptoms your child is experiencing.

What is in this leaflet

1. What **CEFPODOXIME 40 mg / 5 ml UNICORN** is and what it is used for

2. What you need to know before you give **CEFPODOXIME 40 mg / 5 ml UNICORN** to your child

3. How to use **CEFPODOXIME 40 mg / 5 ml UNICORN**

4. Possible side effects

5. How to store **CEFPODOXIME 40 mg / 5 ml UNICORN**

6. Contents of the pack and other information

1. What CEFPODOXIME 40 mg / 5 ml UNICORN is and what it is used for

CEFPODOXIME 40 mg / 5 ml UNICORN belongs to the antibiotic group of medicines known as the cephalosporins.

CEFPODOXIME 40 mg / 5 ml UNICORN is used in children for the treatment of bacterial infections of the ear, throat and lungs such as otitis media, tonsillitis, pharyngitis and pneumonia.

2. What you need to know before you use CEFPODOXIME 40 mg / 5 ml UNICORN

Do not give CEFPODOXIME 40 mg / 5 ml UNICORN to your child:

- If your child is hypersensitive (allergic) to cefpodoxime or any of the other ingredients of **CEFPODOXIME 40 mg / 5 ml UNICORN** listed in section 6.
- If your child has ever had a bad reaction, or been allergic to cephalosporins.
- If your child has phenylketonuria (an inherited defect of protein metabolism) as **CEFPODOXIME 40 mg / 5 ml UNICORN** contains a source of phenylalanine (a protein) in the form of aspartame.
- If your child is under 1 year old.
- **CEFPODOXIME 40 mg / 5 ml UNICORN** must not be taken by patients who are pregnant or breastfeeding.

Special care should be taken with CEFPODOXIME 40 mg / 5 ml UNICORN:

- If your child is allergic (hypersensitive) to any ingredients of **CEFPODOXIME 40 mg / 5 ml UNICORN**, or other antibiotics including cephalosporins and penicillins. Signs of an allergic reaction include a rash, swallowing or breathing problems, and swelling of the lips, face, throat and tongue.

- If your child develops diarrhoea, particularly if severe and/or persistent, occurring during treatment or in the initial weeks following treatment with **CEFPODOXIME UNICORN 40 mg / 5 ml**. This may be signs of a serious disease called pseudomembranous colitis (an inflammatory disease affecting the colon, caused by the bacterium, *Clostridium difficile).*
- If your child suffers from any kidney problems.
- If you have been told by your doctor that your child has an intolerance to some sugars, especially sucrose, contact your doctor before giving **CEFPODOXIME 40 mg / 5 ml UNICORN** (see important information about some of the ingredients of **CEFPODOXIME 40 mg / 5 ml UNICORN**).
- In patients who are pregnant or trying to become pregnant.

You MUST tell your doctor before using **CEFPODOXIME 40 mg / 5 ml UNICORN** if any of the above applies.

Other medicines and CEFPODOXIME 40 mg / 5 ml UNICORN

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

Tell your doctor if you are taking any of the following medicines:

1. The following medicines may decrease the effects of **CEFPODOXIME 40 mg / 5 ml UNICORN**
   - antacids (used to neutralize acid in the stomach)
   - ranitidine (medicines used to treat heartburn)

   Antacids and anti-heartburn medicines should be taken 2 - 3 hours after **CEFPODOXIME 40 mg / 5 ml UNICORN**.

2. The following medicines may increase the effects of **CEFPODOXIME 40 mg / 5 ml UNICORN**

   - probenecid (used for gout)

3. **CEFPODOXIME 40 mg / 5 ml UNICORN** may increase the activity of the following medicines:

   - warfarin (used to treat blood clots for example)

4. **CEFPODOXIME 40 mg / 5 ml UNICORN** may decrease the activity of the following medicines:

   - oestrogens (in contraceptives)

5. Taking **CEFPODOXIME 40 mg / 5 ml UNICORN** with aminoglycosides (an antibiotic) and/or certain strong diuretics (water tablets), may be toxic to the kidneys.

These medicines may interact with **CEFPODOXIME 40 mg / 5 ml UNICORN.**
Before you stop taking any of your medicines, please talk to your doctor first.

If your child needs to take any blood, urine or diagnostic tests, please ensure that your doctor knows as **CEFPODOXIME 40 mg / 5 ml UNICORN** may interfere with the test results.

Pregnancy and Breastfeeding:

Patients who are pregnant or breastfeeding, or who may be pregnant or are planning to have a baby, should consult their doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy

Safety of **CEFPODOXIME 40 MG / 5 ML UNICORN** in pregnant women has not been established, it is therefore not advisable to take **CEFPODOXIME UNICORN 40 MG / 5 ML** during pregnancy.

Breastfeeding

CEFPODOXIME 40 MG / 5 ML UNICORN is eliminated in human breast milk, therefore either breastfeeding or treatment of the mother should be stopped.

Driving and using machines:

Care should be taken by patients who are going to drive or perform skilled tasks as they may experience dizziness whilst taking **CEFPODOXIME 40 mg / 5 ml UNICORN.**

It is not always possible to predict to what extent **CEFPODOXIME 40 mg / 5 ml UNICORN** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **CEFPODOXIME 40 mg / 5 ml UNICORN** affects them.

Important information about some of the ingredients of CEFPODOXIME 40 mg / 5 ml UNICORN

CEFPODOXIME 40 mg / 5 ml UNICORN contains aspartame and sucrose:

Aspartame:

CEFPODOXIME 40 mg / 5 ml UNICORN must not be given to children with phenylketonuria (an inherited defect of protein metabolism), since the formulation contains a source of phenylalanine (a protein) in the form of aspartame.

Sucrose:

If you have been told by your doctor that your child cannot tolerate or digest some sugars, talk to your doctor before giving your child **CEFPODOXIME 40 mg / 5 ml UNICORN.**

Sodium benzoate:

Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to use CEFPODOXIME 40 mg / 5 ml UNICORN

Younger children and infants:

Do not share medicines prescribed for your child with any other person.

Give **CEFPODOXIME 40 mg / 5 ml UNICORN** to your child exactly as your doctor has told you. The amount of medicine to be taken depends on the weight and age of the child to be treated. Carefully read the pharmacist's label. Check with your doctor or pharmacist if you are not sure. The usual dose is given twice a day (morning and evening) with food.

SHAKE THE BOTTLE BEFORE USE.

Your doctor will tell you how long your treatment with **CEFPODOXIME 40 mg / 5 ml UNICORN** will last. The pharmacist will usually give you the exact amount of medicine. If you have the impression that the effect of **CEFPODOXIME 40 mg / 5 ml UNICORN** is too strong or too weak for your child, tell your doctor or pharmacist.

If you use more CEFPODOXIME 40 mg / 5 ml UNICORN than you should:

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

If you forget to give CEFPODOXIME 40 mg / 5 ml UNICORN:

If you have missed a dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take **CEFPODOXIME 40 mg / 5 ml UNICORN** at the next regularly scheduled time. Do not take a double dose to make up for the forgotten individual doses.

If you stop using CEFPODOXIME 40 mg / 5 ml UNICORN:

Do not stop giving the medicine to your child even if your child is feeling better. If you stop giving **CEFPODOXIME 40 mg / 5 ml UNICORN** before the course is complete, your child's condition may reoccur or get worse.

4. Possible side effects

CEFPODOXIME 40 mg / 5 ml UNICORN can have side effects.

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

- blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu-like symptoms and fever. 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 something called **'Toxic epidermal necrolysis'**
- a rash, joint pain, swallowing or breathing problems, swelling of the lips, face, throat or tongue.

These are very serious side effect. If your child shows any of the above signs, he / she may have had a serious reaction to **CEFPODOXIME 40 mg / 5 ml UNICORN**. Your child may need urgent medical attention or hospitalisation.

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

- a skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious skin allergy called **'erythema multiforme'**
- your child gets infections more easily than usual. This could be because of a blood disorder. This is more likely if your child is taking **CEFPODOXIME 40 mg / 5 ml UNICORN** for a long time
- a severe infection of the lining of the bowel, characterised by diarrhoea, fever and abdominal pain. This may be something called **'Pseudomembranous colitis'**
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.
- Your child may also be more pale than normal. This could be because of a serious type of anaemia.
- superinfection (a second infection which occurs during the course of the existing infection, by other bacteria or organisms resistant to **CEFPODOXIME 40 mg / 5 ml UNICORN**), including fungal infections such as oral or vaginal thrush.

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

- nausea (feeling sick) or vomiting (being sick)
- stomach pains

Less frequent side effects:

- headaches
- feeling dizzy
- paraesthesia (pins and needles; numbness or tingling feelings)
- tinnitus (ringing in the ears)
- dyspepsia
- flatulence
- liver problems (fever, itching skin without rash, yellowing of the skin and eyes, feeling generally unwell)
- asthenia (unusual tiredness or weakness).

Frequency unknown side effects:

- seizures
- hearing loss

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

Not all side effects reported for **CEFPODOXIME 40 mg / 5 ml UNICORN** are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking **CEFPODOXIME 40 mg / 5 ml UNICORN**, please consult your health care provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found on-line under SAHPRAs publications: https://www.sahpra.org.za/Publications/Index/8.
Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to enquiries@unicornpharma.co.za.
By reporting side effects, you can help provide more information on the safety of **CEFPODOXIME 40 mg / 5 ml UNICORN.**

5. How to store CEFPODOXIME 40 mg / 5 ml UNICORN

Store all medicines out of reach of children.

- Store at or between 2 °C – 8 °C (in a refrigerator).
- **DO NOT FREEZE.**
- **SHAKE BOTTLE BEFORE USE.**
- Keep the bottle tightly closed.
- Protect from light and moisture.
- Do not store in a bathroom.
- The shelf life of the suspension is 10 days.
- 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 CEFPODOXIME 40 mg / 5 ml UNICORN CONTAINS:

- **The active ingredient:**

Each 5 ml spoonful of liquid contains 40 mg of cefpodoxime.

- **The other ingredients are:**

Anhydrous citric acid,

carboxymethyl cellulose sodium,

silica (colloidal anhydrous),

hydroxypropyl cellulose,

maize starch,

microcrystalline cellulose

spectracol yellow iron oxide (E172) and

artificial banana flavour spray dry (containing modified starch (E1450), nature identical flavoring substances, propylene glycol (E1520), natural flavoring substances and artificial flavoring substances)

Contains sugar / sweetener:

Sucrose (2464.67 mg / 5 ml) and aspartame (20,00 mg / 5 ml).

Contains preservative:

Sodium benzoate 0,2 % *m/v*).

What CEFPODOXIME 40 mg / 5 ml UNICORN looks like and contents of the pack

CEFPODOXIME 40 mg / 5 ml UNICORN:

Almost white to pale yellow coloured powder which has been diluted with water by your pharmacist. The reconstituted suspension is an off-white to pale yellow suspension with a characteristic fruity odour.

CEFPODOXIME 40 mg / 5 ml UNICORN:

Is packed in a round, translucent, HDPE bottle with a white, polypropylene, child

resistant cap with liner.

Holder of Certificate of Registration

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