PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

CEPTOMAX 200 mg/5 mL powder for oral suspension.

Azithromycin dihydrate 200 mg/5 mL powder for oral suspension

Contains sugar: sucrose

Read all this leaflet carefully before you start taking CEPTOMAX.

- 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.
- **CEPTOMAX** 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 **CEPTOMAX** is and what it is used for.

2. What you need to know before you take **CEPTOMAX.**

3. How to take **CEPTOMAX.**

4. Possible side effects.

5 How to store **CEPTOMAX.**

6. Contents of the pack and other information.

1. **What CEPTOMAX is and what is it used for:**

This medicine contains azithromycin, which is one of a group of antibiotics called macrolides. It is used to treat infections caused by certain bacteria and other micro-organisms which include:

Adults and children over 45kg

- chest, throat, or nasal infections (such as bronchitis, pneumonia, tonsillitis, sore throat (pharyngitis) and sinusitis)
- skin and soft tissue infections (such as an abscess or boil)

Children: 1 year and over (under 45 kg)

- ear infections
- tonsillitis and a sore throat (pharyngitis)

2. **What you need to know before you take CEPTOMAX:**

*Do not take **CEPTOMAX**:*

If you or your child is allergic to azithromycin or any other macrolide antibiotic such as erythromycin or clarithromycin or any of the ingredients listed in section 6. An allergic reaction may cause skin rash or wheezing.

If you are taking any ergot derivatives such as ergotamine (used to treat migraine) as these medicines should not be taken together with **CEPTOMAX.**

Warnings and precautions

*Talk to your doctor or health care provider before taking **CEPTOMAX.** Special care should be taken with **CEPTOMAX:***

- ***CEPTOMAX*** *can cause serious allergic reactions (see section 4. Possible side effects) including oedema (build-up of fluid in your body), anaphylaxis (a sever, life threatening allergic reaction which causes difficulty in breathing and shock),* acute generalised exanthematous pustulosis (small blisters filled with white/yellow fluid), Stevens Johnson syndrome (blistering of the skin, mouth, eyes, and genitals), toxic epidermal necrolysis (blistering and peeling of your skin), and drug reaction with eosinophilia and systemic symptoms(fever, swollen glands and an extensive skin rash involving your liver.) Stop taking **CEPTOMAX** and consult your doctor immediately.
- If you have kidney problems
- If you have heart conditions
- If you have diabetes
- If you have liver problems: your doctor may need to monitor your liver function or stop the treatment
- If you suffer from myasthenia gravis (a condition that causes certain muscles to become weak)

Tell your doctor immediately if you feel your heart beating in your chest or have an abnormal heartbeat or get dizzy or faint or suffer from any muscle weakness when taking **CEPTOMAX.**

If you develop diarrhoea or loose stools during or after treatment, consult your doctor. Do not take any medicine to treat your diarrhoea without first checking with your doctor. If your diarrhoea continues, please inform your doctor.

Other medicines and CEPTOMAX:

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

CEPTOMAX may interact with the medicines listed below:

- ergot or ergotamine, see 'Warnings and precautions' section (used to treat migraines and cluster headaches)
- warfarin or any similar medicine to prevent blood clots
- ciclosporin (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow)
- antacids (for indigestion)
- digoxin (used to treat heart failure)
- colchicine (used for gout and familial Mediterranean fever)
- atorvastatin (used for cholesterol) it may cause muscle pain.
- cisapride (used for reflux and constipation)
- fluconazole (anti-fungal)
- zidovudine (anti-retroviral used in HIV)
- amiodarone (medicines that suppresses abnormal rhythms of the heart)
- citalopram (antidepressant)
- moxifloxacin, levofloxacin (fluoroquinolone antibiotics that are approved to treat or prevent certain bacterial infections)

CEPTOMAX with food, drink, and alcohol:

CEPTOMAX suspension is not affected by food or drink.

Pregnancy, breastfeeding and fertility:

The safety of **CEPTOMAX** in pregnancy has not yet been established and should only be used if your doctor prescribes it for you. If you are breast-feeding, **CEPTOMAX** will only be prescribed to you if there are no other alternatives available. It is not known if **CEPTOMAX** affects fertility. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines:

CEPTOMAX may cause you to feel dizzy or impair your eyesight which can have an effect on your ability to drive or use machines. It is not always possible to predict to what extent **CEPTOMAX** 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 **CEPTOMAX** affects them.

CEPTOMAX 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.

3. **How to take CEPTOMAX:**

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

   Always take **CEPTOMAX** exactly as your doctor, or pharmacist has told you.

   Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with **CEPTOMAX** will last. Do not stop treatment early, complete the course. If you have the impression that the effect of **CEPTOMAX** is too strong or too weak, tell your doctor or pharmacist. **CEPTOMAX** suspension is generally used for children under 45 kg. It may also be used in adults and older children who have difficulty swallowing capsules.

The usual dose is:

Adults and children over 45 kg:

The recommended dose is 500 mg (12.5 mL) taken as a single dose, for 3 days.

Children under 45 kg

The recommended dose in children is 10 mg for each kg of bodyweight, given as a single daily dose for 3 days,

Patients with kidney and liver problems:

You should tell your doctor if you/your child have kidney or liver problems as your doctor may need to alter the normal dose.

How to give CEPTOMAX suspension in children less than 3 years of age.

If your child is under three years of age or weighs up to 15 kg in bodyweight, you should measure the dose as clearly as possible using the 10 mL oral dosing syringe provided. The syringe is graduated in 0.25 mL divisions.

Administration of medicine with a syringe:

1. Shake the bottle before use and remove the cap.

2. Check the dispensing label attached to the bottle by your pharmacist/
3. Measure the required dosage using the syringe provided
4. If large air bubbles form in the syringe, slowly push the plunger back into the syringe. This will force the medicine back into the bottle. Repeat step 3.
5. Make sure the patient is supported in an upright position.
6. Point the syringe towards the inside of the patient's cheek and slowly push down the plunger: Do not squirt the medicine out quickly.
7. Wash the syringe as instructed:
    - Pull the plunger out of the syringe and wash both parts in warm running water or soak them in sterilizing solution used for baby's feeding utensils.
    - Once the components have dried, push the plunger back into the syringe and store together with the medicine, in a safe place out of the reach of children.

If you take more CEPTOMAX than you should:

If you/your child take too much **CEPTOMAX** they may feel unwell. Tell your doctor or contact your nearest hospital casualty department immediately. Take any remaining medicine with you.

If you forget to take a dose of CEPTOMAX:

If you forget to take **CEPTOMAX** take it as soon as you can. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking CEPTOMAX

If you/your child stop taking **CEPTOMAX** too soon, the infection may return. Take **CEPTOMAX** for the full time of treatment, even when you/your child begin to feel better.

4. Possible side effects

CEPTOMAX can have side effects.

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

*If any of the following happens, stop taking/using **CEPTOMAX,** and tell your doctor immediately or go to the casualty department at your nearest hospital:*

- sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash, or itching (especially affecting the whole body)
- severe skin rash causing redness and flaking
- Serious skin reactions:
    - blistering of the skin, mouth, eyes, and genitals (Stevens-Johnson Syndrome (SJS))
    - blistering of the skin, severe skin reaction (Toxic Epidermal Necrosis (TEN))
    - skin rash accompanied by other symptoms such as fever, swollen glands and an increase of eosinophils (a type of white blood cell). A rash appears as small, itchy red bumps (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))

- skin eruption that is characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (Acute Generalized Exanthematous Pustulosis (AGEP)).

These are all very serious side effects. If you have them, you may have had a serious reaction to ***CEPTOMAX****. You 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:

- severe or prolonged diarrhoea, which may have blood or mucus in it, during or after treatment with **CEPTOMAX** as this may be a sign of serious bowel inflammation
- rapid or irregular heartbeat
- low blood pressure
- heart palpitations
- chest pain

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:

- Headache
- diarrhoea,
- vomiting,
- abdominal pain,
- nausea

Less frequent side effects:

- Oral or vaginal thrush,
- bacterial and fungal infections,
- inflamed throat,
- gastroenteritis (infectious diarrhoea),
- nasal congestion,
- lack of taste,
- numbness or feeling of “pins and needles”,
- loss of appetite,
- feeling nervous,
- sleeplessness (insomnia),
- agitation,
- dizziness,
- sleepiness,
- poor hearing or ringing in the ears,
- hot flushes,
- loss of breath,
- general loss of strength,
- constipation,
- stomach pain associated with diarrhoea and fever,
- indigestion,
- muscle pain,
- back pain,

- neck pain,
- swelling,
- general loss of strength,
- fever,
- general discomfort,
- abnormal lab tests (e.g. blood and liver test, your doctor will inform you)

Reporting of side effects

If you get side effects, talk to your doctor or 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://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf. By reporting side effects, you can help provide more information on the safety of **CEPTOMAX**.

5. How to store CEPTOMAX

- Store all medicine out of reach of children.
- Store at or below 30 °C for up to 5 days after reconstitution or for 24 months before reconstitution.
- Store in the original package / container
- Keep the container tightly closed
- Protect from light / moisture

6. Contents of the pack and other information

What CEPTOMAX contains:

Active substance: Azithromycin dihydrate

Other ingredients: Banana flavor, cherry flavor, hydroxypropyl cellulose, sodium benzoate, sodium phosphate tribasic- anhydrous, sucrose, xanthan gum.

What CEPTOMAX looks like and contents of the pack

Powder for oral suspension.

White coloured, cherry scented, fluid, homogeneous granules free from particles which constitutes white or off-white suspension after reconstitution with water.

The dry powder mixture is filled in a natural HDPE bottle closed with a polypropylene cap, with a white coloured induction foil, enclosed in a cardboard box containing a patient information leaflet, a dose graduated syringe (5 mL), a two-sided plastic spoon (2.5 – 5 mL), and a 15 mL polypropylene measuring cup.

Holder of Certificate of Registration

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Access to the corresponding Professional information.

A copy of the professional Information is contained in the packaging of

CEPTOMAX.

Follow the link for the corresponding Professional Information for Avaxiga: pi-pil-repository.innovata.co.za,

Alternatively, please scan the QR code below: