PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ZINUROZ 250 (film-coated tablets)

ZINUROZ 500 (film-coated tablets)

Cefuroxime axetil

ZINUROZ 250 contains mannitol (50 mg per tablet)

ZINUROZ 500 contains mannitol (100 mg per tablet)

Read all of this leaflet carefully before you start taking ZINUROZ

- 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.
- ZINUROZ tablets have 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 ZINUROZ is and what it is used for

2. What you need to know before you take ZINUROZ

3. How to take ZINUROZ

4. Possible side effects

5. How to store ZINUROZ

6. Contents of the pack and other information

1. What ZINUROZ is and what it is used for

ZINUROZ tablets is an antibiotic that belongs to the group of medicines called cephalosporins. Cefuroxime kills a wide range of bacteria.

ZINUROZ tablets are used to treat infections of the:

- throat and tonsils
- ear
- sinuses
- lungs or chest
- bladder (or urinary tract)

ZINUROZ can also be used:

- to treat Lyme disease (an infection spread by parasites called ticks).

Your doctor may test the type of bacteria causing your infection and monitor whether the bacteria are sensitive to ZINUROZ during your treatment.

2. What you need to know before you take ZINUROZ

You should not take ZINUROZ tablets:

- If you are hypersensitive (allergic) to cefuroxime or any of the other ingredients of ZINUROZ tablets (listed in section 6).
- If you are allergic to other cephalosporins or to any other type of beta-lactam antibiotic (penicillins, monobactams and carbapenems).

Warnings and precautions

Take special care with ZINUROZ tablets:

- if you are allergic to penicillin and other beta-lactam antibiotics, as you may have an increased chance of being allergic to ZINUROZ tablets as well.

- if you develop a serious skin reaction consisting of severe blisters and bleeding in the lips, eyes, mouth, nose and genitals, large blisters and ends with peeling of layers skin, flu-like symptoms or itchy spots similar to measles rash which starts on limbs, face or other body parts.
- if you develop a high temperature (fever), chills, headache, muscle pain and skin rash while being treated with ZINUROZ tablets for Lyme disease. This may be Jarisch-Herxheimer reaction. Symptoms usually last a few hours or up to one day. Contact a doctor or nurse immediately if you get any of these symptoms.
- if you develop stomach cramps and tenderness, severe and watery or bloody diarrhoea, and fever while taking ZINUROZ tablets or in the first weeks after treatment. This may be an indication of a serious bowel inflammation (pseudomembranous enterocolitis). Please consult your doctor immediately.
- if you have to go for blood tests as ZINUROZ tablets can affect the results of a test for blood sugar levels, or a blood screen called the Coombs test. If you need a blood test, tell the person taking the sample that you are taking ZINUROZ tablets.

Other medicines and ZINUROZ

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

Medicines used to reduce the amount of acid in your stomach (e.g. antacids used to treat heartburn) can affect how ZINUROZ tablets work.

ZINUROZ tablets may reduce the effectiveness of the contraceptive pill.

If you are taking probenecid (medicine used to prevent gout), the blood concentration of cefuroxime may increase and may lead to a worsening of side effects.

If you are taking medicines to thin your blood, let your doctor, pharmacist or other healthcare provider know.

ZINUROZ with food, drink and alcohol

Take ZINUROZ tablets half an hour after food. This will help to make the treatment more effective.

Pregnancy, breastfeeding and fertility

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.

Tell your doctor if you intend to become pregnant, or if you are planning to breastfeed your baby.

Driving and using machines

ZINUROZ tablets can make you dizzy, therefore do take care until you know how ZINUROZ tablets affects your ability to drive and operate machinery.

3. How to take ZINUROZ

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

Always take ZINUROZ tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If your symptoms do not improve within a few days, or if they become worse, check with your doctor.

Adults:

- Infection of sinuses and bronchitis: 250 mg twice daily for 7 days (range 5 to 10 days).
- Infection of the bladder: 250 mg twice daily for 7 days (range 5 to 10 days).
- Lyme disease: Adults and children over 12 years of age: 500 mg twice daily for 20 days.

If you take more ZINUROZ 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 take too much ZINUROZ tablets you may have neurological disorders, in particular you may be more likely to have fits (seizures).

If you forget to take ZINUROZ

If you miss a dose, do not worry, and take it as soon as you remember. Do not take two doses together. If it is almost time for your next dose, wait until then.

If you stop taking ZINUROZ

It is important that you take the full course of ZINUROZ tablets. Don't stop unless your doctor advises you to – even if you are feeling better. If you don't complete the full course of treatment, the infection may come back.

4. Possible side effects

ZINUROZ tablets can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Jarisch-Herxheimer reaction (see "Warnings and precautions").
- Abdominal or stomach cramps, abdominal tenderness, watery and severe diarrhoea which may also be bloody, and fever.
- Skin rash, which may blister, and looks like small targets (central dark spot surrounded by a paler area, with a dark ring around the edge), this is called Erythema Multiforme (EM).
- A widespread rash with blisters and peeling skin (these may be signs of Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN)).

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

- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.
- Difficulty breathing.

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:

- Fungal infections (such as *Candida*).
- An increase in a type of white blood cell (eosinophilia).
- Headache.
- Dizziness.
- Diarrhoea.
- Feeling sick (nausea).
- Stomach pain.
- An increase in liver enzymes.

Less-frequent side effects:

- Positive Coomb's test.
- A decrease in the number of blood platelets (cells that help blood to clot) (thrombocytopenia).
- A decrease in the number of white blood cells (leukopenia).
- Vomiting.
- Skin rashes.

The frequency of the following side effects is unknown:

- Red blood cells destroyed too quickly (haemolytic anaemia).
- High temperature (fever).

- Allergic skin reactions that can cause swelling, itching and a rash (urticaria).

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 ZINUROZ.

Suspected side effects can also be reported directly to the HCR via https://pvi1j.solutions.iqvia.com or adverse.event.sac@sandoz.com

5. How to store ZINUROZ

- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN**.
- Store at or below 25 °C.
- Do not remove the blisters from the carton until required for use.

6. Contents of the pack and other information

What ZINUROZ tablets contains

The active substance is cefuroxime axetil.

Each ZINUROZ 250 film-coated tablet contains cefuroxime axetil equivalent to 250 mg cefuroxime.

Each ZINUROZ 500 film-coated tablet contains cefuroxime axetil equivalent to 500 mg cefuroxime.

The other excipients are:

Excipient core: Copovidone, croscarmellose sodium, crospovidone, magnesium stearate, mannitol granulated, microcrystalline cellulose, silica colloidal anhydrous, sodium lauryl sulphate, talc.

Excipient coating: Hypromellose, polyethylene glycol, polysorbate 80, titanium dioxide (E171).

What ZINUROZ looks like and contents of the pack

ZINUROZ 250: white to slightly yellowish, biconvex, scored on both sides, oblong film-coated tablets.

ZINUROZ 500: white to slightly yellowish, biconvex, oblong film-coated tablets.

Printed cardboard cartons containing 10 or 100 tablets in Alu/Alu blister with PE coating or unit dose Alu/Alu blister with polyamide/PE coating or blister aluminium foil with polyester/PE coating.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

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Registration number

ZINUROZ 250: 37/20.1.1/0055

ZINUROZ 500: 37/20.1.1/0056

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07