PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ZINOXIME 250 mg film-coated tablets

ZINOXIME 500 mg film-coated tablets

Cefuroxime axetil

Sugar free.

Read all of this leaflet carefully before you start taking ZINOXIME.

- 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.
- ZINOXIME 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 ZINOXIME is and what it is used for
2. What you need to know before you take ZINOXIME
3. How to take ZINOXIME
4. Possible side effects
5. How to store ZINOXIME
6. Contents of the pack and other information.

1. What ZINOXIME is and what it is used for

ZINOXIME is an antibiotic which helps to treat certain bacterial infections.

ZINOXIME is used to treat tonsil, ear, nose, throat, respiratory and bladder infections. It is also

used in the treatment of Lyme disease (a bacterial infection you get from the bite of an infected tick).

2. What you need to know before you take ZINOXIME

Do not take ZINOXIME

- If you are hypersensitive (allergic) to cephalosporin antibiotics, cefuroxime or to any of the other ingredients of ZINOXIME (listed in section 6).
- If you are hypersensitive (allergic) to penicillin and other beta-lactam antibiotics.

Warnings and precautions

Take special care with ZINOXIME:

- If you have a history of stomach or bowel disease.
- If you have a kidney problem, as your doctor may adjust the dose.
- If you have porphyria (a group of rare disorders that results from a buildup of natural chemicals called porphyrins in your body).
- If you have had a previous allergic reaction to penicillin or another beta lactam antibiotic.

Tell your doctor if you are testing for sugar in your urine or doing a Coomb's test (antiglobulin test) as ZINOXIME may affect the results of these tests.

Pseudomembranous colitis may occur. If you develop abdominal or stomach cramps, abdominal tenderness, serve and watery diarrhoea (which may be bloody) and fever, report the symptoms to your doctor immediately.

Children and adolescents

ZINOXIME is not for use in children below 3 months of age as the safety and effectiveness are not known in this age group.

Other medicines and ZINOXIME

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:

- Probenecid (medicine used to treat gout).
- Medicines used to treat heartburn and/or indigestion.
- Oral contraceptives (medicines used to prevent a pregnancy).
- Oral anticoagulants (medicines used to prevent blood clots).
- Medicines that affect the kidneys such as certain water tablets (e.g. furosemide) and aminoglycoside antibiotics (e.g. gentamicin).

ZINOXIME with food, drink and alcohol

See section 3.

Pregnancy and breastfeeding

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 health care provider for advice before taking this medicine.

The safety of ZINOXIME during pregnancy and breastfeeding has not been established.

Driving and using machines

ZINOXIME may cause headache and dizziness, which may affect your ability to drive a vehicle and use machines. It is not always possible to predict to what extent ZINOXIME may interfere with your daily activities. You should ensure that you do not engage in the above activities until you know how ZINOXIME affects you.

ZINOXIME contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially

sodium free.

3. How to take ZINOXIME

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

Always take ZINOXIME 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 ZINOXIME will last. If you have the impression that the effect of ZINOXIME is too strong or too weak, tell your doctor or pharmacist.

Your doctor will decide on the dose and duration of your treatment depending on the type and severity of the infection.

The usual course of treatment ranges from 5 to 10 days.

ZINOXIME should be taken in two daily doses.

ZINOXIME should be taken half an hour after food.

Due to the bitter taste of ZINOXIME, the tablets should not be crushed.

If you take more ZINOXIME than you should

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

If you forget to take ZINOXIME

If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

4. Possible side effects

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

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

- Seizures (fits).
- Diarrhoea, in some case accompanied by blood in the stools.
- Yellowing of the skin, eyes, dark urine and tiredness which may be symptoms of liver problems.
- Blood in the urine, passing less or more urine than is normal for you, swelling of any area of the body.
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- Skin reactions, such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS) and erythema multiforme. These reactions can be life-threatening and are characterised by a painful, blistering skin rash .
- Weight loss, fevers, night sweats, fatigue, cough, chest pain, weakness, confusion, and coma.
- Bleeding or bruising more easily than normal.

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:

- White patches or sores in your mouth.

- Dry, itchy or sore vagina, vaginal discharge, light vaginal bleeding or spotting.
- Headache, dizziness.
- Nausea (feeling sick), diarrhoea (frequent, loose, watery stools), stomach pain.

Less frequent side effects

- Painful urination or urine that has a bad odour.
- Hearing loss in children with meningitis.
- Vomiting (being sick).

Side effects with frequency unknown

- Anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration).
- Swelling below the surface of the skin.
- Blood test that indicates an increase in your liver enzymes and a positive antiglobulin (Coomb's) test.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of Zinoxime.

5. How to store ZINOXIME

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Keep the blister strip in the outer carton until required for use.
- 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 ZINOXIME contains

The active substance is cefuroxime axetil.

ZINOXIME 250 mg: Each film-coated tablet contains cefuroxime axetil (amorphous) equivalent to cefuroxime 250 mg.

ZINOXIME 500 mg: Each film-coated tablet contains cefuroxime axetil (amorphous) equivalent to cefuroxime 500 mg.

The other ingredients are microcrystalline cellulose, croscarmellose sodium; hydrogenated vegetable oil; hypromellose, macrogol 400, colloidal silica (anhydrous), sodium laurilsulfate and titanium dioxide.

What ZINOXIME looks like and contents of the pack

ZINOXIME 250 mg: White to off-white, film-coated, capsule shaped tablets with ‘A33’ debossed on one side and plain on the other side.

ZINOXIME 500 mg: White to off-white, film-coated, capsule shaped tablets with ‘A34’ debossed on one side and plain on the other side.

Tablets are packed in cold form laminate: 25-micron polyamide / 45-micron aluminium foil / 60-micron PVC film as the forming material and aluminium foil as the lidding material.

Each blister contains 10 tablets.

Pack size: 10 tablets.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

This leaflet was last revised in

Date of registration: 18 April 2008

Date of revision of the text: 18 March 2024

Registration numbers

ZINOXIME 250 mg: 41/20.1.1/0752

ZINOXIME 500 mg: 41/20.1.1/0753