CLEAN AMENDED PATIENT INFORMATION LEAFLET

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

- Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor or your pharmacist.

- **LIZORP** 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.

SCHEDULING STATUS

S4

1. WHAT LIZORP CONTAINS:

LIZORP 250 mg:

Each film coated tablet contains Cefprozil (Monohydrate) equivalent to anhydrous Cefprozil 250 mg.

LIZORP 500 mg:

Each film coated tablet contains Cefprozil (Monohydrate) equivalent to anhydrous Cefprozil 500 mg.

The other ingredients of **LIZORP** are cellulose microcrystalline (Avicel PH 102); lactose; magnesium stearate; sodium starch glycolate (Type A) and Opadry Orange YS-1-2456. The imprinting materials used in **LIZORP** are Opacode Black S-1-17734 and isopropyl alcohol.

2. WHAT LIZORP IS USED FOR:

LIZORP is a broad spectrum cephalosporin antibiotic that is used to treat the following mild to moderately severe infections:

- Upper respiratory tract infections – tonsilitis and pharyngitis.
- Middle ear infection (otitis media).
- Sinusitis.
- Lower respiratory tract infections - bronchitis.

- Uncomplicated skin and skin structure infections.
- Uncomplicated urinary tract infections.

3. BEFORE YOU TAKE LIZORP:

Do not take LIZORP:

- If you are allergic to cefprozil, cephalosporin antibiotics, other beta-lactam group of antibiotics or any of the other ingredients of **LIZORP**.
- Children that are younger than 1 year old.
- If you are pregnant or breastfeeding.

Take special care with LIZORP:

- Before you start taking **LIZORP**, tell you doctor if have had any allergic reactions to **LIZORP**, other cephalosporin antibiotics, penicillins, or other medicine. If you are allergic to penicillin, you should exercise extra caution as cross-sensitivity with **LIZORP** has been noted.
- Stop taking **LIZORP** immediately if you develop an allergic reaction (difficult breathing and/or swelling of lips, face and throat) and seek emergency medical help.
- **LIZORP** may cause pseudomembranous colitis. Contact your doctor if you have any of these symptoms- abdominal cramps, bloody stools, diarrhoea and/ or fever.
- Tell your doctor if you have or had kidney disease in the past as your dosage of **LIZORP** may have to be adjusted.
- If you take **LIZORP** for a prolonged period, you may develop a superinfection meaning that a new infection can result that is resistant to **LIZORP.** Consult your doctor if you experience fever or chills, lower back or side pain, painful or difficult urination.
- Tell your doctor if you are taking water pills. Taking water pills together with **LIZORP** may affect kidney function.

- Positive direct Coombs tests have been reported during treatment with cephalosporin antibiotics such as **LIZORP**. If you have a positive result for the Coombs test it means that you have low red blood cell counts.

Taking LIZORP with food and drink:

LIZORP is not affected by food, and tablets may be taken before, during or after meals.

Pregnancy and breastfeeding:

Safety of use in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding your baby while taking **LIZORP**, please consult your doctor, pharmacist or other health care professional for advice.

Driving and Using Machinery

LIZORP may cause dizziness. If you feel dizzy while taking **LIZORP** do not drive and do not use hazardous tools or machines.

LIZORP contains lactose. If you have hereditary problems of galactose intolerance, the lapp lactase deficiency or glucose-galactose malabsorption, you should not take **LIZORP**.

Taking other medicines with

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

- Other cephalosporin antibiotics- Taking **LIZORP** with other cephalosporin antibiotics may cause a decrease in your Vitamin K production which can affect blood clotting. Your doctor may advise you to take additional Vitamin K supplements especially if you are malnourished or seriously ill.
- Aminoglycoside antibiotics- taking **LIZORP** with aminoglycoside antibiotics can lead to kidney damage.
- Potent diuretics/ water tablets- taking **LIZORP** with diuretics may affect kidney function.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **LIZORP** tablets with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE LIZORP:

Always take **LIZORP** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **LIZORP** is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will prescribe an appropriate dose for you according to you condition.

If you take more LIZORP than you should:

- Symptoms of overdose may include: seizures, severe abdominal cramps and vomiting.

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

If you forget to take LIZORP:

If you forget to take a dose of your medicine, take it as soon as you remember, and then continue as before. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

5. POSSIBLE SIDE EFFECTS:

LIZORP can have side-effects.

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

- Anaphylaxis characterised by: Skin rash, hives, difficulty breathing, swelling of your face,
- lips, tongue, or throat and / or shock.

These are all very serious side effects. If you have them, you have had a serious allergic reaction to **LIZORP**. You may need urgent medical attention or hospitalization.

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

- black, tarry stools, chills, fever, cough, shortness of breath, unusual tiredness and weakness.
- Pseudomembranous colitis (abdominal cramps, watery, severe diarrhoea, fever).
- blistering, peeling, loosening of skin and mucous membranes, which may involve the eyes or other organ systems.
- chest pain, chills, fever, unusual bleeding and bruising.
- hives or wells, itching and redness of skin.
- Serum sickness (fever, joint pain, skin rash).
- abdominal or stomach pain, clay-coloured stools, dark urine, headache, loss of appetite, unpleasant smelling of breath.
- Superinfection (fever, hoarseness or cough, lower back or side pain, painful or difficult urination, decreased amount of urine).

Tell your doctor if you notice any of the following side-effects:

- dizziness
- hyperactivity
- headache
- nervousness

- lack of or trouble sleeping
- confusion
- drowsy or sleepiness
- nausea,
- vomiting, diarrhoea, abdominal pain
- irritation or infection of the vagina that may result itching, burning sensation, pain and/ or discharge from the vagina.

Not all side effects reported for **LIZORP** are included in this leaflet. Should your general health worsen while taking **LIZORP**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF LIZORP:

Keep all medicines out of the reach and sight of children. Store at or below 30 ºC.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF LIZORP:

1.PVC/ACLAR-Aluminium blister packs:

Tablets are packed in 250 Micron Clear PVC Film Laminated with 23 Micron Aclar (width 200 mm) as the forming material and aluminium foil 25 microns (width 194 mm) as the lidding material. Each blister contains 10 tablets.

Pack size: 10's: Each carton contains 1 blister of 10 tablets along with package insert.

2. PVC/PVdC-Aluminium blister packs:

Tablets are packed in clear 250 Micron PVC coated with 60 gsm PVdC (width 200 mm) as the forming material and aluminium foil 25 microns (width 194 mm) as the lidding material. Each blister contains 10 tablets.

Pack size: 10's: Each carton contains 1 blister of 10 tablets along with package insert.

8. IDENTIFICATION OF LIZORP:

a. LIZORP 250 mg:

Orange coloured, biconvex, film-coated caplets, imprinted "C 16" with black ink on one side.

b. LIZORP 500 mg:

White, biconvex, film-coated caplets, imprinted "C17" with black ink on one side.

9. REGISTRATION NUMBER / REFERENCE NUMBER:

LIZORP 250 mg: 41/20.1.1/0586

LIZORP 500 mg: 41/20.1.1/0587

10.NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Aurogen South Africa (Pty) Ltd

Woodhill Office Park, Building 1,

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11. DATE OF PUBLICATION:

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