APPROVED PATIENT INFORMATION LEAFLET

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LIZORP SUSPENSION 125 mg/5 ml (Powder for suspension)

LIZORP SUSPENSION 250 mg/5 ml (Powder for suspension)

Cefprozil (monohydrate)

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** 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.

1. WHAT LIZORP CONTAINS

The active substance is cefprozil monohydrate.

LIZORP SUSPENSION 125 mg/5 ml:

Each 5 ml (after reconstitution) contains cefprozil monohydrate equivalent to 125 mg anhydrous cefprozil and sodium benzoate 0,064 % *m/v* as preservative. Contains sugar.

LIZORP SUSPENSION 250 mg/5 ml:

Each 5 ml (after reconstitution) contains cefprozil monohydrate equivalent to 250 mg anhydrous cefprozil and sodium benzoate 0,064 % *m/v* as preservative. Contains sugar.

The other ingredients are: sucrose, sodium chloride, citric acid monohydrate, simethicone emulsion, polysorbate 80, aspartame, glycine, carmellose sodium, dispersible cellulose, colloidal anhydrous silica, bubble gum flavour and FD & C yellow colourant (C.I. No: 15985).

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/give LIZORP:

- If you are allergic to cephalosporin antibiotics or any of the other ingredients of **LIZORP**.
- To children that are younger than 1 year old.
- If you are pregnant or breastfeeding your baby.

Take special care with LIZORP:

- Before you start taking **LIZORP**, tell your doctor if you have had any previous 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 and seek emergency medical help in the case of an acute reaction (difficult breathing and/or swelling of lips, face and throat).
- **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.

Taking LIZORP with food and drink:

LIZORP is not affected by food, and the suspension may be administered/taken before, during or after meals.

Pregnancy and Breastfeeding:

The safety of **LIZORP** in pregnancy and breastfeeding has not been established.

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

Important information about some of the ingredients of LIZORP:

LIZORP contains 8,4 mg of phenylalanine per 5 ml of reconstituted suspension for both the 125 mg/5 ml and 250 mg/5 ml dosage strengths. If you suffer with phenylketonuria you may need to monitor your intake of phenylalanine.

Taking other medicines with LIZORP:

When you are taking **LIZORP**, it is especially important that your health care professional knows if you are taking any of the following:

- Other cephalosporin antibiotics – concurrent use can alter/ reduce vitamin K synthesis. You may have to take prophylactic vitamin K therapy if you are taking cephalosporin antibiotics are used for long periods especially if you are malnourished or seriously ill.
- Aminoglycoside antibiotics - concurrent therapy with cephalosporins may damage your kidney.
- Diuretics- concurrent treatment with cephalosporins can affect functioning of your kidney.

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

3. 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.

Adults and children over 12 years: The dose is determined by your doctor. The usual dose is 250 mg or 500 mg taken every 24 hours (once a day) or every 12 hours (twice a day) for 10 days. Take **LIZORP** exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Children (1 year to 12 years): Dose is based on body weight and must be determined by your doctor.

If you have kidney disease, your doctor may need to adjust your dosage.

If you have impaired liver function, no dosage adjustment is necessary.

If you take more LIZORP than you should:

In cases of severe overdosage, haemodialysis will help to remove cefprozil from the body.

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

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.

4. POSSIBLE SIDE-EFFECTS

LIZORP can have side-effects.

Get emergency medical help if you have any of these signs of an allergic reaction:

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

The following serious side-effects may occur and require medical attention:

- Eosinophilia (black, tarry stools, chills, fever, cough, shortness of breath, unusual tiredness and weakness).
- Pseudomembranous colitis (abdominal cramps, watery, severe diarrhoea, fever).
- Erythema Multiforme or Stevens- Johnsons syndrome (blistering, peeling, loosening of skin and mucous membranes, which may involve the eyes or other organ systems)
- Leukopenia, neutropenia or thromobocytopenia (chest pain, chills, fever, unusual bleeding and bruising).
- Urticaria (hives or wells, itching and redness of skin).
- Serum sickness (fever, joint pain, skin rash).
- Hepatic dysfunction including cholestasis (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).
- Serum sickness (fever, joint pain, skin rash).

Tell your doctor if you notice any of the following side-effects and they worry you or if any of these symptoms are severe or do not go away:

- dizziness
- hyperactivity
- headache
- nervousness
- insomnia

- confusion
- somnolence
- nausea,
- vomiting, diarrhoea, abdominal pain
- genital or vaginal pruritus (itching of the genital or vaginal area, pain during intercourse, thick, white vaginal discharge).

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

6. STORING AND DISPOSING OF LIZORP SUSPENSION

Store in a cool, dry place at or below 30 ºC.

Storage for Reconstituted Suspension:

Once reconstituted, the suspension should be kept in a refrigerator (2 to 8 ºC) and used within 14 days. SHAKE WELL BEFORE USE. Discard any unused solution. Keep the container well closed. Protect from light.

Store all medicines out of reach of children.

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 SUSPENSION

LIZORP SUSPENSION 125 mg/5 ml:

The granules are packed in a colourless 115 ml HDPE translucent, round bottle with a 28 mm neck closed with a white opaque 28 mm child resistant closure with an induction sealing wad, together with a 20 ml measuring cup.

Pack size: 60 ml of suspension after reconstitution.

LIZORP SUSPENSION 250 mg/5 ml:

The granules are packed in a colourless 115 ml HDPE translucent, round bottle with a 28 mm

neck closed with a white opaque 28 mm child resistant closure with an induction sealing wad, together with a 20 ml measuring cup.

Pack size: 60 ml of suspension after reconstitution.

8. IDENTIFICATION OF LIZORP SUSPENSION

LIZORP SUSPENSION 125 mg/5 ml:

For Dry Powder: White to off white granular powder with bubble gum flavour.

For Reconstituted Suspension: Light orange suspension with bubble gum flavour.

LIZORP SUSPENSION 250 mg/5 ml:

For Dry Powder: White to off white granular powder with bubble gum flavour.

For Reconstituted Suspension: Light orange suspension with bubble gum flavour.

9. REGISTRATION NUMBER/REFERENCE NUMBER

LIZORP SUSPENSION 125 mg/5 ml: 43/20.1.1/0535.

LIZORP SUSPENSION 250 mg/5 ml: 43/20.1.1/0536.

10. NAME AND ADDRESS OF REGISTRATION HOLDER-

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