LIZORP SUSPENSION
P1533138

LIZORP SUSPENSION
P1533138

AUROGEN

PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK

SKEDULERINGSTATUS

S4

EIENDOMSNAAM (en doseervorm)
LIZORP SUSPENSION 125 mg/5 ml (Poeier vir suspensie)
LIZORP SUSPENSION 250 mg/5 ml (Poeier vir suspensie)

SAMESTELLING

LIZORP SUSPENSION 125 mg/5 ml:

Elke 5 ml (na hersamestelling) bevat sefprosielmonohidraat ekwivalent aan 125 mg anhidriese sefprosiel en natriumbensoaat 0,064 % *m/v* as preserveermiddel. Bevat suiker en soeter: sukrose 2176,37 mg en 15 mg aspartaam onderskeidelik per 5mL hersaamgestelde suspensie.

LIZORP SUSPENSION 250 mg/5 ml:

Elke 5 ml (na hersamestelling) bevat sefprosielmonohidraat ekwivalent aan 250 mg anhidriese sefprosiel en natriumbensoaat 0,064 % *m/v* as preserveermiddel. Bevat suiker en soeter: sukrose 2059,79 mg en 15 mg aspartaam onderskeidelik per 5mL hersaamgestelde suspensie.

Die ander bestanddele van die formulering is sukrose, natriumchloried, sitroensuurmonohidraat, simetikoonemulsie, polisorbaat 80, aspartaam, glisien, karmellose-natrium, mikrokristallyne sellulose/ karboksimetielsellulose-natrium, silika kolloïdaal anhidries, Bobbelgomgeur (PWD # 730) en Kleur FD&C Geel Nr. 6(C.I. Nr: 15985).

FARMAKOLOGIESE KLASSIFIKASIE

A 20.1.1 Breë- en mediumspektrum antibiotika

FARMAKOLOGIESE WERKING

Sefprosiel behoort aan 'n subgroep beta-laktaam-antibiotika, die sefalosporiene. Dit is bakteriedodend en werk deur sintese van die bakteriële selwand te inhibeer.

Mikrobiologie

Die bakteriedodende werking van sefprosiel spruit voort uit inhibisie van selwandsintese.

Aërobe, gram-positief

LET WEL: Sefprosiel is onaktief teen metisillien-weerstandige stafilokokke en *E. faecium.*

Aërobe, gram-negatief

LET WEL: Sefprosiel is onaktief teen die meeste stamme van *Actinetobacter, Enterobacter, Morganella morganii, Proteus vulgaris, Providencia, Pseudomonas* en *Serratia.*

Anaërobe

Die meeste stamme van die *Bacteroides fragilis* groep is weerstandig teen sefprosiel. Ander weerstandige organismes sluit in:*Clostridium difficile; C. perfringens; Fusobacterium* spp.; *Peptostreptococcus* spp.; *Prevotella melaninogenica* (eers bekend as *Bacteroides melaninogenicus) Propionibacterium acnes.*

In vitro sensitiwiteit impliseer nie noodwendig kliniese doeltreffendheid nie.

Farmakokinetiese eienskappe

Sefprosiel is 'n oraal toegediende middel wat meer aktief is as die eerste-generasie sefalosporiene teen penisillien-sensitiewe streptokokke, *E. coli, P. mirabilis, Klebsiella* spp., en *Citrobacter* spp. Dit het 'n serumhalfleeftyd van 1,2 tot 1,4 uur.

Na orale toediening word sefprosiel ongeveer 96 % in beide vastende en nie-vastende proefpersone geabsorbeer.

Plasmaproteïenbinding is ongeveer 36 % en is onafhanklik van konsentrasie in die reikwydte van 2 µg/ml tot 20 µg/ml.

By individue met normale nierfunksie, akkumuleer sefprosiel nie in die plasma nie.

Die verlenging van die plasmahalfleeftyd is verwant aan die graad van renale disfunksie by pasiënte met verminderde renale funksie. By pasiënte met volkome afwesigheid van renale funksie, kon daar aangedui word dat die plasmahalfleeftyd van sefprosiel so lank as 5,9 uur is.

Die halfleeftyd word tydens hemodialise verkort tot 2,1 uur. Uitskeidingsroetes by pasiënte met uitgesproke ingekorte renale funksie is nie bepaal nie (Sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS** en **DOSIS EN GEBRUIKSAANWYSINGS**).

Die gemiddelde AOK wat by bejaarde pasiënte (65-jarige ouderdom) waargeneem word, is ongeveer 35-60 % hoër as dié by jong volwassenes en die gemiddelde AOK by vrouens is ongeveer 15-20 % hoër as by mans.

Die grootte van hierdie ouderdom- en geslagsverwante variasies in die farmakokinetika van sefprosiel is nie genoeg om dosisaanpassings te verg nie.

By pasiënte met ingekorte hepatiese funksie, word geen beduidende verskille in farmakokinetiese parameters waargeneem nie, as dit met normale kontroles vergelyk word.

Toereikende data oor CSF-vlakke van sefprosiel is nie beskikbaar nie.

INDIKASIES

LIZORP word aangedui vir die behandeling van pasiënte met ligte tot matig ernstige infeksies veroorsaak deur vatbare stamme van die aangewese mikroörganismes wat hierna gelys word.

Boonste lugweg:

Faringitis/tonsilitis veroorsaak deur *Streptococcus pyogenes*. Die gebruiklike middel van keuse in die behandeling en voorkoming van Streptokokkale infeksies, insluitend die profilakse van rumatiekkoors, is penisillien.

LIZORP is effektief in die uitwissing van *Streptococcus pyogenes* uit die nasofarinks. Uitgebreide data wat die doeltreffendheid van **LIZORP** bewys in die daaropvolgende voorkoming van rumatiekkoors is egter tans nie beskikbaar nie.

Otitis media:

Otitis media veroorsaak deur *Streptococcus pneumoniae, Haemophilus influenzae* en *Moraxella (Branhamella) catarrhalis*. In die behandeling van otitis media en sinusitis as gevolg van beta-laktamase-produserende organismes, het **LIZORP** bakteriologiese uitwissingskoerse gehad wat effens laer was as dié wat waargeneem word met 'n produk wat 'n spesifieke beta-laktamase-inhibeerder bevat. Wanneer die gebruik van **LIZORP** oorweeg word, behoort die algehele uitwissingskoerse opgeweeg te word teen die vatbaarheidspatrone van die algemene mikrobes in 'n gegewe geografiese gebied en die verhoogde potensiaal vir toksisiteit met produkte wat beta-laktamase-inhibeerders bevat.

Onderste lugweg:

Sekondêre bakteriële infeksie van akute brongitis en akute bakteriële verergering van chroniese brongitis veroorsaak deur *Streptococcus pneumoniae, Haemophilus influenzae* (beta-laktamase-positiewe en - negatiewe stamme) en *Moraxella (Branhamella) catarrhalis.*

Vel- en velstruktuur:

Ongekompliseerde vel- en velstruktuurinfeksies veroorsaak deur *Staphylococcus aureus* (insluitend penisillinase-produserende stamme) en *Streptococcus pyogenes.*

Urienweg:

Ongekompliseerde urienweginfeksies, insluitend akute sistitis by vrouens veroorsaak deur *Escherichia coli, Klebsiella pneumoniae* en *Proteus mirabilis.*

Kultuur- en vatbaarheidstoetse behoort uitgevoer te word wanneer toepaslik om die vatbaarheid van die oorsaaklike organisme teen **LIZORP** te bepaal.

KONTRA-INDIKASIES

LIZORP is teenaangedui by pasiënte wat vorige hipersensitiwiteitsreaksies teen die sefalosporienklas van antibiotika, penisilline of ander beta-laktaam-antibiotika, of enige komponent van die formulering, gehad het.

Kinders onder die ouderdom van 1 jaar.

Swangerskap en laktasie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

Voordat terapie met **LIZORP** begin word, behoort versigtige navraag gedoen te word om vas te stel of die pasiënte vorige hipersensitiwiteitsreaksies teen **LIZORP**, ander sefalosporiene, penisilline, of ander medisyne gehad het. Indien **LIZORP** aan penisillien-sensitiewe pasiënte gegee moet word, behoort versigtigheid uitgeoefen te word omdat kruis-sensitiwiteit tussen beta-laktaam-antibiotika gedokumenteer is. Indien 'n allergiese reaksie teen **LIZORP** voorkom, moet **LIZORP** gestaak word.

Ernstige akute hipersensitiwiteitsreaksies mag noodbehandelingsmaatreëls verg.

Pseudomembraneuse kolitis kan voorkom.

Pediatriese Gebruik:

Veiligheid en doeltreffendheid by kinders jonger as 1 jaar is nie vasgestel nie. Akkumulasie van ander sefalosporienantibiotika in pasgeborenes (as gevolg van die verlengde medisyne halfleeftyd in hierdie ouderdomsgroep), is aangemeld.

Evaluering van renale status voor en tydens terapie word aanbeveel, veral in pasiënte wat ernstig siek is.

By pasiënte met bekende of vermoede renale inkorting (sien **DOSIS EN GEBRUIKSAANWYSINGS**), behoort versigtige kliniese waarneming en toepaslike laboratoriumstudies uitgevoer te word voor en tydens terapie.

Die totale daaglikse dosis **LIZORP** behoort by hierdie pasiënte verminder te word omdat hoë en/of langdurige plasmakonsentrasies van antibiotika by sulke individue selfs met gewone dosisse, kan voorkom. Sefalosporiene, insluitend **LIZORP**, behoort met omsigtigheid toegedien te word aan pasiënte wat gelyktydige behandeling met potente diuretika ontvang omdat dit vermoed word dat hierdie middels 'n nadelige effek op renale funksie het.

Langdurige gebruik van **LIZORP** mag oormatige groei van nie-vatbare organismes veroorsaak. Versigtige observasie van die pasiënt is essensieel. Indien superinfeksie voorkom tydens terapie, moet toepaslike maatreëls toegepas word.

Positiewe direkte Coombs-toetse is tydens behandeling met sefalosporienantibiotika aangemeld. Persone met fenielketonurie: **LIZORP** (125 mg/5 ml en 250 mg/5 ml) bevat fenielalanien (van aspartaam) 8,4 mg per 5 ml hersaamgestelde suspensie.

Effekte op die vermoë om te bestuur of masjiene te gebruik
LIZORP mag duiseligheid veroorsaak wat die vermoë om te bestuur of masjiene te gebruik mag affekteer. Hierdie aktiwiteite behoort nie uitgevoer te word nie totdat die invloed van **LIZORP** op die individue bepaal is.

INTERAKSIES

LIZORP kan die sintese van vitamien K inhibeer deur onderdrukking van die dermflora. Profilaktiese vitamien K-terapie word aanbeveel wanneer **LIZORP** vir lang tydperke gebruik word in wangevoede pasiënte of pasiënte wat ernstig siek is. Gelyktydige toediening van **LIZORP** en aminoglikosied-antibiotika veroorsaak nefrotoksisiteit.

Laboratoriumtoetsinteraksies:

LIZORP mag 'n vals-positiewe reaksie vir glukose in die urine met koper-reduksietoetse (Benedict of Fehling se oplossing of met Clinitest tablette) veroorsaak, maar nie met ensiem-gebaseerde toetse vir glikosurie nie (glukose-oksidase). 'n Vals-negatiewe reaksie mag in die ferrisianiedtoets vir bloedglukose voorkom. Die teenwoordigheid van **LIZORP** in die bloed meng nie met die essai vir kreatinien in plasma of urine deur middel van die alkaliese pikraatmetode, in nie.

SWANGERSKAP EN LAKTASIE

Die veiligheid van gebruik in swangerskap en laktasie is nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS

Aanwysings vir hersamestelling:

LIZORP SUSPENSION 125 mg/5 ml en **LIZORP SUSPENSION 250 mg/5 ml:**

60 ml:

Vir hersamestelling voeg 42 ml gesuiwerde water by, draai die bottel om en skud goed totdat al die poeier gedispergeer is.

100 ml:

Vir hersamestelling voeg 70 ml gesuiwerde water by, draai die bottel om en skud goed totdat al die poeier gedispergeer is.

Volwassenes en kinders ouer as 12 jaar:

LIZORP word oraal vir 'n tydperk van 10 dae vir die behandeling van infeksies as gevolg van vatbare bakterieë toegedien in die volgende:

Infeksies van die boonste lugweg:	500 mg elke 24 uur
Infeksies van die onderste lugweg:	500 mg elke 12 uur
Sinusitis:	250 mg elke 12 uur of 500 mg elke 12 uur
Ongekompliseerde urienweginfeksies:	500 mg elke 24 uur
Infeksies van die vel en velstrukture:	250 mg elke 12 uur of 500 mg elke 12 of 24 uur

Kinders:

Die aanbevole dosis **LIZORP** vir kinders tussen 1 jaar en 12-jarige ouderdom is die volgende:

Infeksies van die boonste lugweg, faringitis of tonsilitis:	7,5 mg/kg elke 12 uur
Otitis media:	15 mg/kg elke 12 uur
Infeksies van die vel en velstrukture:	20 mg/kg een keer daagliks
Sinusitis:	7,5 - 15 mg/kg elke 12 uur

Renale Inkorting:

LIZORP mag aan pasiënte met ingekorte renale funksie toegedien word. Geen dosisaanpassing is nodig vir pasiënte met kreatinienopruimingswaardes > 30 ml/min. Vir dié met kreatinienopruimingswaardes =30 ml/min, behoort 50 % van die standaard dosis op die standaard doseringsinterval gegee te word.

LIZORP word gedeeltelik deur hemodialise verwyder; dus behoort **LIZORP** na die voltooiing van hemodialise toegedien te word.

Hepatiese Inkorting:

Geen dosisaanpassing is vir pasiënte met ingekorte hepatiese funksie nodig nie.

NEWE-EFFEKTE

Bloed- en limfatiese sisteemversteurings:
Frekwent: Eosinofilie.
Minder frekwent: Neutropenie, trombositopenie. Verlengde PT/ INR is waargeneem.

Immuunsisteemversteurings:
Minder frekwent: Anafilakse, koors, serumsiekte en pseudomembraneuse kolitis.
Frekwensie onbekend: Angio-edeem.

Senusisteemversteurings:
Die volgende newe-effekte is aangemeld en die frekwensies is onbekend:
Duiseligheid, hiperaktiwiteit, hoofpyn, senuagtigheid, slaaploosheid, verwarring en lomerigheid.

Gastroïntestinale versteurings:
Frekwent: Naarheid, braking, diarree en abdominale pyn.

Hepatobiliêre versteurings:
Minder frekwent: Cholestatiese geelsug.
Die volgende newe-effekte is aangemeld en die frekwensies is onbekend:
Verhogings van AST, ALT, alkaliese fosfatase, bilirubienwaardes.

Vel- en onderhuidse weefselversteurings:
Minder frekwent: Erythema multiforme, Stevens-Johnson-sindroom, superinfeksie, veluitslag, urtikarie.

Renale en urinêre versteurings:
Die volgende newe-effekte is aangemeld en die frekwensies is onbekend:
Verhogings in bloedureum en serumkreatinien.

Voortplantingsisteem- en borsversteurings:
Minder frekwent: Algemene pruritus en vaginitis.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

(Sien **NEWE-EFFEKTE**)

In geval van ernstige oordosis, veral by pasiënte met gekompromitteerde renale funksie, sal hemodialise help om **LIZORP** uit die liggaam te verwyder.

IDENTIFIKASIE

LIZORP SUSPENSION 125 mg/5 ml:
Vir Droë Poeier: Wit tot naaswit granulêre poeier met 'n bobbelgomgeur.
Vir Hersaamgestelde Suspensie: Ligte oranje suspensie met 'n bobbelgomgeur.

LIZORP SUSPENSION 250 mg/5 ml:
Vir Droë Poeier: Wit tot naaswit granulêre poeier met 'n bobbelgom geur.
Vir Hersaamgestelde Suspensie: Ligte oranje suspensie met 'n bobbelgomgeur.

AANBIEDING

LIZORP SUSPENSION 125 mg/5 ml:

1) Die granules word verpak in 'n kleurlose 115 ml HDPE deurskynende, ronde bottel met 'n 28 mm nek wat met 'n wit ondeurskynende 28 mm peutervrye sluitstuk met 'n induksie seël pluisie verseël word, saam met 'n 20 ml maatkoppie.

Verpakkingsgrootte: 60 ml suspensie na hersamestelling.

2) Die granules word verpak in 'n kleurlose 150 ml HDPE deurskynende, ronde bottel met 'n 28 mm nek wat met 'n wit ondeurskynende 28 mm peutervrye sluitstuk met 'n induksie seël pluisie verseël word, saam met 'n 20 ml maatkoppie.

Verpakkingsgrootte: 100 ml suspensie na hersamestelling.

LIZORP SUSPENSION 250 mg/5 ml:

Die granules word verpak in 'n kleurlose 150 ml ml HDPE deurskynende, ronde bottel met 'n 28 mm nek wat met 'n wit ondeurskynende 28 mm peutervrye sluitstuk met 'n induksie seël pluisie verseël word, saam met 'n 20 ml maatkoppie.

Verpakkingsgrootte: 100 ml suspensie na hersamestelling.

BEWARINGSINSTRUKSIES

Bewaar in 'n koel, droë plek by of benede 30 °C.

Berging van hersaamgestelde suspensie:

Nadat dit hersaamgestel is, behoort die suspensie in 'n yskas gehou te word (2 tot 8 °C) en binne 14 dae gebruik te word. SKUD GOED VOOR GEBRUIK. Raak van enige ongebruikte oplossing ontslae. Hou die houer dig gesluit. Beskerm teen lig.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMERS

LIZORP SUSPENSION 125 mg/5 ml: 43/20.1.1/0535
LIZORP SUSPENSION 250 mg/5 ml: 43/20.1.1/0536

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

AUROGEN SOUTH AFRICA (EDMS..) BPK.
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Suid-Afrika

DATUM VAN PUBLIKASIE VAN DIE VOUBILJET:

DATUM VAN REGISTRASIE:

5 Junie 2014

DATUM VAN HERSIENING:

18 September 2021

DETACH BEFORE DISPENSING

Nie alle newe-effekte wat vir **LIZORP** aangemeld is, word in hierdie brosjure ingesluit nie. Indien jou algemene gesondheid sou vererger of as jy enige nadelige effekte ondervind terwyl jy **LIZORP** neem, moet jy asseblief jou dokter, apteker of ander gesondheidsorgdeskundige vir advies raadpleeg.

6. BERGING EN WEGDOENING VAN LIZORP SUSPENSION

Bewaar in 'n koel, droë plek by of benede 30 °C.

Berging van hersaamgestelde suspensie:

Nadat dit hersaamgestel is, behoort die suspensie in 'n yskas gehou te word (2 tot 8 °C) en binne 14 dae gebruik te word. SKUD GOED VOOR GEBRUIK. Raak van enige ongebruikte oplossing ontslae. Hou die houer dig gesluit. Beskerm teen lig. Bewaar alle medisyne buite bereik van kinders.

Gee alle ongebruikte medisyne terug aan jou apteker. Moenie ongebruikte medisyne in dreine of rioolsisteme (bv. toilette) weggooi nie.

7. AANBIEDING VAN LIZORP SUSPENSION

LIZORP SUSPENSION 125 mg/5 ml:

1) Die granules word verpak in 'n kleurlose 115 ml HDPE deurskynende, ronde bottel met 'n 28 mm nek wat met 'n wit ondeurskynende 28 mm peutervrye sluitstuk met 'n induksie seël pluisie verseël word, saam met 'n 20 ml maatkoppie.

Verpakkingsgrootte: 60 ml suspensie na hersamestelling.

2) Die granules word verpak in 'n kleurlose 150 ml HDPE deurskynende, ronde bottel met 'n 28 mm nek wat met 'n wit ondeurskynende 28 mm peutervrye sluitstuk met 'n induksie seël pluisie verseël word, saam met 'n 20 ml maatkoppie.

Verpakkingsgrootte: 100 ml suspensie na hersamestelling.

LIZORP SUSPENSION 250 mg/5 ml:

Die granules word verpak in 'n kleurlose 150 ml ml HDPE deurskynende, ronde bottel met 'n 28 mm nek wat met 'n wit ondeurskynende 28 mm peutervrye sluitstuk met 'n induksie seël pluisie verseël word, saam met 'n 20 ml maatkoppie.

Verpakkingsgrootte: 100 ml suspensie na hersamestelling.

8. IDENTIFIKASIE VAN LIZORP SUSPENSION

LIZORP SUSPENSION 125 mg/5 ml:
Vir Droë Poeier: Wit tot naaswit granulêre poeier met 'n bobbelgomgeur.
Vir Hersaamgestelde Suspensie: Ligte oranje suspensie met 'n bobbelgomgeur.

LIZORP SUSPENSION 250 mg/5 ml:
Vir Droë Poeier: Wit tot naaswit granulêre poeier met 'n bobbelgom geur.
Vir Hersaamgestelde Suspensie: Ligte oranje suspensie met 'n bobbelgomgeur.

9. REGISTRASIENOMMERS

LIZORP SUSPENSION 125 mg/5 ml: 43/20.1.1/0535
LIZORP SUSPENSION 250 mg/5 ml: 43/20.1.1/0536

10. NAAM EN BESIGHEIDSADRES VAN DIE REGISTRASIEHOUER

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11. DATUM VAN PUBLIKASIE

DATUM VAN REGISTRASIE:

5 Junie 2014

DATUM VAN HERSIENING:

18 September 2021

PASIËNTINLIGTINGSPAMFLET

S4

LIZORP SUSPENSION 125 mg/5 ml (Poeier vir suspensie)
LIZORP SUSPENSION 250 mg/5 ml (Poeier vir suspensie)

Sefprosielmonohidraat

Lees hierdie hele brosjure versigtig voordat jy begin om LIZORP te neem.
- Hou hierdie brosjure. Jy mag dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter of jou apteker daarvoor.
- **LIZORP** is vir jou persoonlik voorgeskryf en jy behoort nie jou medisyne met ander persone te deel nie. Dit kan hulle skade aandoen, al is hulle simptome dieselfde as joune.

1. WAT LIZORP BEVAT

Die aktiewe stof is sefprosielmonohidraat.

LIZORP SUSPENSION 125 mg/5 ml:

Elke 5 ml (na hersamestelling) bevat sefprosielmonohidraat ekwivalent aan 125 mg anhidriese sefprosiel en natriumbensoaat 0,064 % *m/v* as preserveermiddel. Bevat suiker. Bevat suiker en soeter: sukrose 2176,37 mg en 15 mg aspartaam onderskeidelik per 5mL hersaamgestelde suspensie.

LIZORP SUSPENSION 250 mg/5 ml:

Elke 5 ml (na hersamestelling) bevat sefprosielmonohidraat ekwivalent aan 250 mg anhidriese sefprosiel en natriumbensoaat 0,064 % *m/v* as preserveermiddel. Bevat suiker. Bevat suiker en soeter: sukrose 2059,79 mg en 15 mg aspartaam onderskeidelik per 5mL hersaamgestelde suspensie.

Die ander bestanddele is: sukrose, natriumchloried, sitroensuurmonohidraat, simetikoonemulsie, polisorbaat 80, aspartaam, glisien, karmellose-natrium, dispergeerbare sellulose, kolloïdale anhidriese silika, bobbelgomgeur en FD & C geel kleurmiddel (C.I. Nr: 15985).

2. WAARVOOR LIZORP GEBRUIK WORD

LIZORP is 'n breëspektrum sefalosporienantibiotikum wat gebruik word om die volgende ligte tot matig ernstige infeksies te behandel:

- Infeksies van die boonste lugweg - tonsilitis en faringitis
- Infeksie van die middeloor (otitis media)
- Sinusitis
- Infeksies van die onderste lugweg - brongitis
- Ongekompliseerde infeksies van die vel- en velstrukture
- Ongekompliseerde urienweginfeksies

3. VOORDAT JY LIZORP NEEM

Moenie LIZORP neem/gee nie:

- Indien jy allergies vir sefalosporienantibiotika of enige van die ander bestanddele van **LIZORP** is.
- Vir kinders wat jonger as 1 jaar oud is.
- Indien jy swanger is of jou baba borsvoed.

Neem spesiale sorg met LIZORP:

- Voordat jy begin om **LIZORP** te neem, moet jy vir jou dokter vertel indien jy enigevorige allergiese reaksies teen **LIZORP**, ander sefalosporienantibiotika, penisilline, of ander medisyne gehad het. Indien jy vir penisillien allergies is, behoort jy ekstra omsigtigheid uit te oefen omdat kruis-sensitiwiteit met **LIZORP** aangeteken is.
- Staak inname van **LIZORP** dadelik indien jy 'n allergiese reaksie (probleme met asemhaling en/of swelling van die lippe, gesig, en keel).
- **LIZORP** mag pseudomembraneuse kolitis veroorsaak. Kontak jou dokter indien jy niersiekte het of dit gehad het in die verlede omdat jou dosis **LIZORP** moontlik sal moet aangepas word.
- Indien jy **LIZORP** vir 'n lang tydperk neem, mag jy 'n superinfeksie ontwikkel. Dit beteken dat 'n nuwe infeksie kan voorkom wat weerstandig is teen **LIZORP**.
- Raadpleeg jou dokter as jy koors of kouekoors, lae rugpyn of pyn in die sy, pynlike of. moeilike urinering ondervind.

Neem van LIZORP met kos en drank:

LIZORP word nie deur kos geaffekteer nie, en die suspensie kan voor, tydens of na maaltye, toegedien/geneem word.

Swangerskap en Borsvoeding:

Die veiligheid van **LIZORP** in swangerskap en borsvoeding is nie vasgestel nie.

Indien jy swanger is of jou baba borsvoed, moet jy asseblief jou dokter, apteker of ander gesondheidsorgdeskundige vir advies raadpleeg voordat jy **LIZORP** neem.

Belangrike inligting oor sommige van die bestanddele van LIZORP:

LIZORP bevat 8,4 mg fenielalanien per 5 ml hersaamgestelde suspensie vir beide die 125 mg/5 ml en die 250 mg/5 ml doseringsterktes. Indien jy aan fenielketonurie ly, sal jy moontlik jou inname van fenielalanien moet moniteer.

Neem van ander medisyne saam met LIZORP:

Wanneer jy **LIZORP** neem, is dit besonder belangrik dat jou gesondheidsorgdeskundige weet indien jy enige van die volgende neem:

- Ander sefalosporienantibiotika - gelyktydige gebruik kan die sterkte van vitamien K verander/verlaag. Jy sal dalk profilaktiese vitamien K-terapie moet neem indien jy sefalosporienantibiotika vir lang tydperke gebruik.
- Aminoglikosied-antibiotika - gelyktydige terapie met sefalosporiene kan die funksionering van jou niere affekteer.
- Diuretika - gelyktydige behandeling saam met sefalosporiene kan jou niere affekteer.

Jy moet altyd jou gesondheidsorgdeskundige vertel indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in).

4. HOE OM LIZORP TE NEEM

Neem **LIZORP** altyd presies volgens jou dokter se instruksies. Jy behoort met jou dokter of apteker te gesels indien jy nie seker is nie. Indien jy onder die indruk verkeer dat die effek van **LIZORP** te sterk of te swak is, gesels met jou dokter of apteker daaroor.

Volwassenes en kinders ouer as 12 jaar: Die dosis sal deur jou dokter bepaal word. Die gebruiklike dosis is 250 mg of 500 mg wat elke 24 uur (een keer per dag) of elke 12 uur (twee keer per dag) vir 10 dae geneem word. Neem **LIZORP** presies volgens instruksies. Moenie meer of minder neem of dit meer dikwels neem as deur jou dokter voorgeskryf nie.

Kinders (1 jaar tot 12 jaar): Die dosis word op liggaamsgewig gebaseer en moet deur jou dokter bepaal word.

Indien jy niersiekte het, sal jou dokter jou dosis moontlik moet aanpas.
Indien jy ingekorte lewerfunksie het, is geen dosisaanpassing nodig nie.

Indien jy meer LIZORP neem as wat jy behoort te neem:

In gevalle van ernstige oordosis, sal hemodialise help om sefprosiel uit die liggaam te verwyder.

In 'n geval van oordosis, raadpleeg jou dokter of apteker. Indien beide nie beskikbaar is nie, moet jy die naaste hospitaal of giftebeersentrum kontak.

Indien jy vergeet om LIZORP te neem:

Indien jy vergeet om 'n dosis van jou medisyne te neem, moet jy dit neem sodra jy daarvan onthou, en dan voortgaan soos tevore. As dit egter amper tyd is vir jou volgende dosis, slaan dan die vergete dosis oor en gaan voort met jou gebruiklike doseringskedule. Moenie 'n dubbele dosis neem om op te maak vir 'n vergete dosis nie.

5. MOONTLIKE NEWE-EFFEKTE

LIZORP kan newe-effekte veroorsaak.

Kry mediese noodhulp indien jy enige van hierdie tekens van 'n allergiese reaksie het:

- Anafilakse gekenmerk deur: Veluitslag, galbulte, probleme met asemhaling, swelling van jou gesig, lippe, tong, of keel en/of skok.

Die volgende ernstige newe-effekte mag voorkom en het mediese aandag nodig:

- Eosinofilie (swart, teeragtige stoelgang, kouekoors, koors, hoes, kortasem, bongewone moegheid en swakheid).
- Pseudomembraneuse kolitis (abdominale krampe, waterige, ernstige diarree, koors).
- Erythema multiforme of Stevens-Johnson-sindroom (blaasvorming, afskilfering, losmaking van die vel en slymvliese, vat die oë of ander orgaansisteme mag betrek)
- Leukopenie, neutropenie of trombositopenie (borspyn, kouekoors, koors, keelpyn, ongewone bloeding en kneusing).
- Urtikarie (galbulte of strieme, jeuk en rooiheid van die vel).
- Serumsiekte (koors, gevrigpyn, veluitslag).
- Hepatiese disfunksie insluitend cholestase (abdominale of maagpyn, klei–kleurige stoelgang, donker urine, hoofpyn, verlies aan aptyt, asem het 'n onaangename reuk).
- Superinfeksie (koors, heesheid of hoes, lae rugpyn of pyn in die sy, pynlike of moeilike urinering, verminderde hoeveelheid urine). Vertel jou dokter indien jy van enige van die volgende newe-effekte bewus word en dit jou bekommer of indien enige van hierdie simptome ernstig word of nie verdwyn nie:
  - duiseligheid
  - hiperaktiwiteit
  - hoofpyn
  - senuagtigheid
  - slaaploosheid
  - verwarring
  - lomerigheid

Professional Information for Medicines for Human Use

SCHEDULING STATUS

S4

PROPRIETARY NAME (and dosage form)

LIZORP SUSPENSION 125 mg/5 ml (Powder for suspension)
LIZORP SUSPENSION 250 mg/5 ml (Powder for suspension)

COMPOSITION

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 and sweetner: sucrose 2176,7 mg and 15 mg aspartame respectively per 5 mL reconstituted suspension.

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 and sweetner: sucrose 2050,79 mg and 15 mg aspartame respectively per 5 mL reconstituted suspension.

The other ingredients of the formulation are sucrose, sodium chloride, citric acid monohydrate, simethicone emulsion, polysorbate 80, aspartame, glycine, carmellose sodium, microcrystalline cellulose/carboxymethylcellulose sodium, silica colloidal anhydrous, Bubble Gum Flavour (PWD # 730) and Colour FD&C Yellow No.6 (C.I. No: 15985).

PHARMACOLOGICAL CLASSIFICATION

A 20.1.1 Broad and medium spectrum antibiotics

PHARMACOLOGICAL ACTION

Cefprozil belongs to a sub-group of beta-lactam antibiotics, cephalosporins. It is bactericidal and acts by inhibiting synthesis of bacterial cell wall.

Microbiology

The bactericidal action of cefprozil results from inhibition of cell-wall synthesis.

Aerobes,gram-positive

NOTE: Cefprozil is inactive against methicillin-resistant staphylococci and *E. faecium.*

Aerobes, gram-negative

NOTE: Cefprozil is inactive against most strains of *Acinetobacter, Enterobacter, Morganella morganii, Proteus vulgaris, Providencia, Pseudomonas* and *Serratia.*

Anaerobes

Most strains of the *Bacteroides fragilis* group are resistant to cefprozil. Other resistant organisms include:

Clostridium difficile; C. perfringens; Fusobacterium spp.; *Peptostreptococcus* spp.; *Prevotella melaninogenica* (formerly known as *Bacteroides melaninogenicus*) *Propionibacterium acnes. In vitro* sensitivity does not necessarily imply clinical efficacy.

Pharmacokinetic properties

Cefprozil is an orally administered agent more active than first-generation cephalosporins against penicillin-sensitive streptococci, *E.coli*, *P. mirabilis*, *Klebsiella* spp., and *Citrobacter* spp. It has a serum half-life of 1,2 to 1,4 hours.

Cefprozil is approximately 96 % absorbed following oral administration in both fasting and non-fasting subjects.

Plasma protein binding is approximately 36 % and is independent of concentration in the range of 2 µg/ml to 20 µg/ml.

In individuals with normal renal function, cefprozil does not accumulate in the plasma. The plasma half-life prolongation is related to the degree of renal dysfunction in patients with reduced renal function. In patients with complete absence of renal function, the plasma half-life of cefprozil has been shown to be as long as 5,9 hours.

The half-life is shortened during haemodialysis to 2,1 hours. Excretion pathways in patients with markedly impaired renal function have not been determined (See **WARNINGS AND SPECIAL PRECAUTIONS** and **DOSAGE AND DIRECTIONS FOR USE**).

The average AUC observed in elderly subjects (65 years of age) is approximately 35 – 60 % higher than that of young adults and the average AUC in females is approximately 15 – 20 % higher than in males. The magnitude of these age and gender-related variations in the pharmacokinetics of cefprozil are not sufficient to necessitate dosage adjustments.

In patients with impaired hepatic function, no significant differences in pharmacokinetic parameters are observed, when compared to normal control subjects.Adequate data on CSF levels of cefprozil are not available.

INDICATIONS

LIZORP is indicated for the treatment of patients with mild to moderately severe infections caused by susceptible strains of the designated micro-organisms listed below.

Upper respiratory tract:

Pharyngitis/tonsillitis caused by *Streptococcus pyogenes*. The usual agent of choice in the treatment and prevention of Streptococcal infections, including the prophylaxis of rheumatic fever, is penicillin. **LIZORP** is effective in the eradication of *Streptococcus pyogenes* from the nasopharynx. However, substantial data establishing the efficacy of **LIZORP** in the subsequent prevention of rheumatic fever are not available at present.

Otitis media:

Otitis media caused by *Streptococcus pneumoniae, Haemophilus influenza* and *Moraxella (Branhamella) catarrhalis.*

In the treatment of otitis media and sinusitis due to beta-lactamase producing organisms, **LIZORP** had bacteriologic eradication rates somewhat lower than those observed with a product containing a specific beta-lactamase inhibitor. In considering the use of **LIZORP**, lower overall eradication rates should be balanced against the susceptibility patterns of the common microbes in a given geographic area and the increased potential for toxicity with products containing beta-lactamase inhibitors.

Lower respiratory tract:

Secondary bacterial infection of acute bronchitis and acute bacterial exacerbation of chronic bronchitis caused by *Streptococcus pneumoniae, Haemophilus influenza* (beta-lactamase positive and negative strains) and *Moraxella* (*Branhamella) catarrhalis.*

Skin and skin structure:

Uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (including penicillinase-producing strains) and *Streptococcus pyogenes.*

Urinary tract:

Uncomplicated urinary tract infections including acute cystitis in women caused by *Escherichia coli, Klebsiella pneumonia* and *Proteus mirabilis*.

Culture and susceptibility testing should be performed when appropriate to determine susceptibility of the causative organism to **LIZORP**.

CONTRA-INDICATIONS

LIZORP is contra-indicated in patients who have had previous hypersensitivity reactions to the cephalosporin class of antibiotics, penicillins or other beta-lactam antibiotics or any component of the formulation.

Children below the age of 1 year.
Pregnancy and lactation.

WARNINGS AND SPECIAL PRECAUTIONS

Before therapy with **LIZORP** is instituted, careful inquiry should be made to determine whether the patients have had previous hypersensitivity reactions to **LIZORP**, other cephalosporins, penicillins, or other medicine. If **LIZORP** is to be given to penicillin-sensitive patients, caution should be exercised because cross-sensitivity among beta-lactam antibiotics has been documented. If an allergic reaction to **LIZORP** occurs, discontinue **LIZORP**. Serious acute hypersensitivity reactions may require emergency treatment measures.

Pseudomembranous colitis can occur.

Paediatric Use:

Safety and efficacy in children below the age of 1 year have not been established. Accumulation of other cephalosporin antibiotics in newborn infants (resulting from prolonged medicine half-life in this age group) has been reported.

Evaluation of renal status before and during therapy is recommended, especially in seriously ill patients. In patients with known or suspected renal impairment (see **DOSAGE AND DIRECTIONS FOR USE**), careful clinical observation and appropriate laboratory studies should be done prior to and during therapy. The total daily dose of **LIZORP** should be reduced in these patients because high and/or prolonged plasma antibiotic concentrations can occur in such individuals from usual doses. Cephalosporins, including **LIZORP**, should be given with caution to patients receiving concurrent treatment with potent diuretics since these agents are suspected of adversely affecting renal function. Prolonged use of **LIZORP** may result in the overgrowth of non-susceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken. Positive direct Coombs tests have been reported during treatment with cephalosporin antibiotics.

Phenylketonurics: **LIZORP** (125 mg/5 ml and 250 mg/5 ml) contains phenylalanine (from aspartame) 8,4 mg per 5 ml reconstituted suspension.

Effects on ability to drive or use machinery

LIZORP may cause dizziness which may affect ability to drive or use machinery. These activities should not be performed until the influence of **LIZORP** on the individual has been determined.

INTERACTIONS

LIZORP can inhibit vitamin K synthesis by suppressing gut flora. Prophylactic vitamin K therapy is recommended when **LIZORP** is used for long periods in malnourished or seriously ill patients. Concomitant administration of **LIZORP** and aminoglycoside antibiotics causes nephrotoxicity.

Laboratory Test Interactions:

LIZORP may produce a false positive reaction for glucose in the urine with copper reduction tests (Benedict's or Fehling's solution or with Clinitest tablets), but not with enzyme-based tests (glucose oxidase) for glycosuria. A false negative reaction may occur in the ferricyanide test for blood glucose. The presence of **LIZORP** in the blood does not interfere with the assay of plasma or urine creatinine by the alkaline picrate method.

PREGNANCY AND LACTATION

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

DOSAGE AND DIRECTIONS FOR USE

Directions for reconstitution:

LIZORP SUSPENSION 125 mg/5 ml and **LIZORP SUSPENSION 250 mg/5 ml:**

60 ml:

For reconstitution add 42 ml of purified water, invert the bottle and shake well until all the powder is dispersed.

100 ml:

For reconstitution add 70 ml of purified water, invert the bottle and shake well until all the powder is dispersed.

Adults and children over 12 years:

LIZORP is administered orally for a period of 10 days in the treatment of infections due to susceptible bacteria in the following:

Upper respiratory infections:	500 mg every 24 hours
Lower respiratory infections:	500 mg every 12 hours
Sinusitis:	250 mg every 12 hours or 500 mg every 12 hours
Uncomplicated urinary tract infections:	500 mg every 24 hours
Skin & skin structure infections:	250 mg every 12 hours or 500 mg every 12 or 24 hours

Children:

The recommended dosing of **LIZORP** for children between 1 year and 12 years of age is the following:

Upper respiratory tract infections, pharyngitis or tonsillitis: 7,5 mg/kg every 12 hours

Otitis media:	15 mg/kg every 12 hours
Skin and skin structure infections:	20 mg/kg once daily
Sinusitis:	7,5 – 15 mg/kg every 12 hours

Renal Impairment:

LIZORP may be administered to patients with impaired renal function. No dosage adjustment is necessary for patients with creatinine clearance values > 30 ml/min. For those with creatinine clearance values =30 ml/min, 50 % of the standard dose should be given at the standard dosing interval. **LIZORP** is in part removed by haemodialysis; therefore, **LIZORP** should be administered after the completion of haemodialysis.

Hepatic Impairment:

No dosage adjustment is necessary for patients with impaired hepatic function.

SIDE EFFECTS

Blood and the lymphatic system disorders:
Frequent: Eosinophilia.
Less frequent: Neutropenia, thrombocytopenia. Prolonged PT/INR has been observed.

Immune system disorders:
Less frequent: Anaphylaxis, fever, serum sickness and pseudomembranous colitis.
Frequency unknown: Angioedema
Nervous system disorders:
The following side effects have been reported and frequencies are unknown:
Dizziness, hyperactivity, headache, nervousness, insomnia, confusion and somnolence.

Gastrointestinal disorders:
Frequent: Nausea, vomiting, diarrhoea and abdominal pain.

Hepato-biliary disorders:
Less frequent: Cholestatic jaundice.
The following side effects have been reported and frequencies are unknown:
Elevations of AST, ALT, alkaline phosphatase, bilirubin values.

Skin and subcutaneous tissue disorders:
Less frequent: Erythema multiforme, Stevens-Johnson syndrome, superinfection, rash, urticaria.

Renal and urinary disorders:
The following side effects have been reported and frequencies are unknown:
Elevations in blood urea and serum creatinine.

Reproductive system and breast disorders:
Less frequent: General pruritus and vaginitis.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT (See **SIDE EFFECTS**)

In case of severe overdosage, especially in patients with compromised renal function, haemodialysis will aid in the removal of **LIZORP** from the body.

IDENTIFICATION

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.

PRESENTATION

LIZORP SUSPENSION 125 mg/5 ml:

1)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.

2) The granules are packed in a colourless 150 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: 100 ml of suspension after reconstitution.

LIZORP SUSPENSION 250 mg/5 ml:

The granules are packed in a colourless 150 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: 100 ml of suspension after reconstitution.

STORAGE INSTRUCTIONS

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

Storage for reconstituted suspension:

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

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS

LIZORP SUSPENSION 125 mg/5 ml: 43/20.1.1/0535
LIZORP SUSPENSION 250 mg/5 ml: 43/20.1.1/0536

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

AUROGEN SOUTH AFRICA (PTY) LTD
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg
South Africa

DATE OF PUBLICATION OF THE PACKAGE INSERT:

DATE OF REGISTRATION:

5 June 2014

DATE OF REVISION:

18 September 2021

P1533138

DETACH BEFORE DISPENSING

6. STORING AND DISPOSING OF LIZORP SUSPENSION

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

Storage for reconstituted suspension:

Once reconstituted, the suspension should be kept in a refrigerator (2 to 8 °C) 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:

1) 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.

2) The granules are packed in a colourless 150 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: 100 ml of suspension after reconstitution.

LIZORP SUSPENSION 250 mg/5 ml:

The granules are packed in a colourless 150 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: 100 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 NUMBERS

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

AUROGEN SOUTH AFRICA (PTY) LTD
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg
South Africa

11. DATE OF PUBLICATION

DATE OF REGISTRATION:

5 June 2014

DATE OF REVISION:

18 September 2021

PATIENT INFORMATION LEAFLET

S4

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 and sweetner: sucrose 2176,7 mg and 15 mg aspartame respectively per 5 mL reconstituted suspension.

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 and sweetner: sucrose 2050,79 mg and 15 mg aspartame respectively per 5 mL reconstituted suspension.

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 (difficulty 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 healthcare 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 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.)

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.

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 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.

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 thrombocytopenia (chest pain, chills, fever, unusual bleeding and bruising)
- Urticaria (hives or welts, itching and redness of skin).
- Serum sickness (fever, joint pain, skin rash).
- Hepatic dysfunction including cholestasis (abdominal or stomach pain, claycoloured 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 healthcare professional for advice.