Pharmacode position may change as per the supplier's m/c requirement

APPROVED
Samantha , 07:25:40, 02/07/2022

LIZORP TABLETS
P1530170

LIZORP TABLETS
P1530170

SKEDULERINGSTATUS

SUID AFRIKA: S4
NAMIBIË: NS2

EIENDOMSNAAM (en doseervorm):
LIZORP 250 mg (tablet)
LIZORP 500 mg (tablet)

SAMESTELLING:
LIZORP 250 mg
Elke filmbedekte tablet bevat sefprosiel (monohidraat) ekwivalent aan anhidriese sefprosiel 250 mg. Suikervry.
LIZORP 500 mg
Elke filmbedekte tablet bevat sefprosiel (monohidraat) ekwivalent aan anhidriese sefprosiel 500 mg. Suikervry.

Die ander bestanddele van **LIZORP** is mikrokristallyne sellulose (Avicel PH 102); magnesiumstearaat; natriumstyselglikolaat (Tipe A) en Opadry Oranje YS-1-2456. Die drukmateriaal wat in **LIZORP** gebruik word, is Opacode Swart S-1-17734 en isopropielalkohol.

FARMAKOLOGIESE KLASSIFIKASIE:
A 20.1.1 Breë- en mediumspektrum antibiotika

FARMAKOLOGIESE WERKING:
Sefprosiel behoort aan 'n sub-groep beta-laktaamantibiotioka, sefalosporiene (tweede generasie). Dit is bakteriedodend en werk deur sintese van die bakteriese selwand te inhibeer.

Mikrobiologie
Sefprosiel besit *in vitro* aktiwiteit teen die gram +ve and -ve bakterië (*in vitro* aktiwiteit beteken nie noodwendig *in vivo* doeltreffendheid nie).

Weerstandige organismes
Aërobe, Gram-positief
Sefprosiel is onaktief teen metisillienweerstandbiedende stafilokokke en *Enterococcus faecium.*
Aërobe, Gram-negatief
Kefprosiel is onaktief die meeste stamme van *Acinetobacter, Enterobacter, Morganella morgani, Proteus vulgaris, Providencia, Pseudomonas* en *Serratia.*
Anaërobe
LET WEL: Die meeste stamme van die *Bacteroides fragilis* groep is weerstandbiedend teen sefprosiel.

INDIKASIES:
LIZORP word aangedui vir die behandeling van pasiënte met gering tot matig ernstige infeksies veroorsaak deur vatbare stamme van mikro-organismes hieronder gelys:
Boonste lugweg
Faringitis / tonsilitis veroorsaak deur *Streptococcus pyogenes.*
LET WEL: Die middel van keuse wat gewoonlik in die behandeling en voorkoming van streptokokinfeksies gebruik word, insluitende die voorkoming van rumatiekkoors, is penisillien. **LIZORP** is doeltreffend in die uitwissing van *Streptococcus pyogenes* vanuit die nasofarinks. Daar bestaan egter nog nie genoeg data vir die bevestiging van die doeltreffendheid van **LIZORP** in die daaropvolgende voorkoming van rumatiekkoors nie.
Otitis media en sinusitis
Otitis media en sinusitis veroorsaak deur *Streptococcus pneumoniae, Haemophilus influenzae* en *Branhamella catarrhalis.*
LET WEL: In die behandeling van otitis media en sinusitis veroorsaak deur beta-laktamaseproduserende organismes, het **LIZORP** effens laer uitwissingskoerse getoon as dié waargeneem in 'n produk wat 'n spesifieke beta-laktamase inhibeerder bevat het. Wanneer die gebruik van **LIZORP** oorweeg word, behoort laer algehele uitwissingskoerse gebalanseer te word met die vatbaarheidspatrone van algemene mikrobes in 'n gegewe geografiese area, asook die toenemende potensiaal vir toksisiteit met produkte wat beta-laktamase inhibeerders bevat.
Benede lugweg
Sekondêre bakteriese infeksie van akute brongitis en akute bakteriese verergering van chroniese brongitis veroorsaak deur *Streptococcus pneumoniae, Haemophilus influenzae* (beta-laktamase positiewe en negatiewe stamme) en *Branhamella catarrhalis.*
Vel en velstruktuur
Ongekompliseerde infeksies van die vel en velstruktuur veroorsaak deur *Staphylococcus aureus* (insluitende penisillinase-produserende stamme) en *Streptococcus pyogenes.*
Urienweg
Ongekompliseerde urienweginfeksies, insluitende akute sistitis in vroue veroorsaak deur *Escherichia coli, Klebsiella pneumoniae* en *Proteus mirabilis.*
LET WEL: Kweking en vatbaarheidstoetsing behoort, wanneer van toepassing, uitgevoer te word om die vatbaarheid van die oorsaaklike organisme teen **LIZORP** vas te stel.

KONTRA-INDIKASIES:

- **LIZORP** word teenaangedui in pasiënte wat voorheen hipersensitiwiteitsreaksies teen die sefalosporienklas van antibiotika, penisillien of beta-laktaamantibiotika, of enige komponent van die formulasie getoon het (sien **"WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS"**).
- Kinders jonger as 1 jaar.
- Swangerskap en laktasie.

WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS:
Voordat terapie met **LIZORP** ingestel word, behoort noukeurige navraag gedoen te word om vas te stel of die pasiënt vorige hipersensitiwiteitsreaksies teen **LIZORP**, ander sefalosporiene, penisilliene of ander medisyne getoon het. As hierdie produk aan penisilliensensitiewe pasiënte toegedien gaan word, behoort sorg aan die dag gelê te word aangesien kruissensitiwiteit tussen die beta-laktaamantibiotika gedokumenteer is. Indien 'n allergiese reaksie teen **LIZORP** voorkom, moet die gebruik van die middel gestaak word. Ernstige akute hipersensitiwiteitsreaksies mag noodbehandelingsmaatreëls vereis.

Pediatriese gebruik
Veiligheid en effektiwiteit in kinders onder die ouderdom van 1 jaar is nie vasgestel nie. Die akkumulasie van ander sefalosporiene in pasgebore babas (weens die lang halfleeftyd van hierdie medisyne in hierdie ouderdomsgroep) is aangemeld.

Pseudomembraneuse kolitis is met die gebruik van **LIZORP** aangemeld. Simptome van pseudomembraneuse kolitis sluit erge, aanhoudende diaree, erge buikkrampe en bloederige stoelgang in. Die uiterste sorg moet aan die dag gele word wanneer **LIZORP** in pasiënte met 'n geskiedenis van gastrointestinale siektes gebruik word. Pasiënte wat erge diaree ondervind terwyl hulle **LIZORP** gebruik moet onmiddellik met die behandeling staak en nood mediese advies inwin.

Evaluering van die nierstatus behoort vóór en gedurende behandeling word aanbeveel, veral in ernstige siek pasiënte. In pasiënte met bekende of vemoedelike belemmerde nierfunksie (sien "**DOSIS EN GEBRUIKSAANWYSINGS**"), behoort noukeurige kliniese observasie en toepaslike laboratoriumtoetse vóór en gedurende terapie uitgevoer te word. Die totale daaglikse dosis **LIZORP** behoort in hierdie pasiënte verminder te word, aangesien hoër en / of langer plasmakonsentrasies van die antibiotika in sulke indiwidue op die normale dosisse mag voorkom. Sefalosporiene, insluitende **LIZORP**, behoort met sorg aan pasiënte wat meegaande terapie met sterk diuretika ontvang, toegedien te word, aangesien daar vermoed word dat hierdie middels 'n nadelige effek op die nierfunksie het.

Die verlengde gebruik van **LIZORP** mag tot oorgroeiing van nie-vatbare organismes lei. Sorgvuldige observasie van die pasiënt is noodsaaklik. Indien superinfeksie gedurende terapie voorkom, behoort toepaslike maatreëls getref te word. Positiewe direkte Coombestoetse is gedurende die gebruik van sefalosporienantibiotika soos **LIZORP**, aangemeld.

LIZORP bevat laktose. Pasiënte met selde voorkomende oorerflike probleme van galaktoseintoleransie, die Lapp Laktasetekort of glukose-galaktose wanabsorpsie behoort nie **LIZORP** te gebruik nie.

Effekte op die vermoe om te bestuur en masjinerie te gebruik
Die potensiaal van duiseligheid behoort in ag geneem te word voordat pasiënte op **LIZORP** bestuur of met masjinerie werk.

INTERAKSIES:
LIZORP kan die sintese van vitamien K inhibeer deur die flora van die dermkanaal te onderdruk wat dan die risiko van bloeding mag verhoog. Daarbenewens was daar berigte van protrombientye wat verleng is by pasiënte wat **LIZORP** en warfarien, in besonder,geneem het. Dosisaanpassing van antikoagulante medisyne mag voor en na behandeling met **LIZORP** noodsaaklik wees.

Die gelyktydige toediening van **LIZORP** en aminoglikosiedantibiotika veroorsaak nefrotoksisiteit.

Interaksies met laboratoriumtoetse
LIZORP mag 'n vals positiewe reaksie vir glukose in die urien toon wanneer kopperreduksietoetse (Benedict- of Fehlingoplossing of met Clinitest tablette) gebruik word, maar nie met ensiemgebaseerde (glukose-oksidase) toetse vir glukosurie nie. 'n Vals negatiewe reaksie mag in die ferrisianiedtoets vir bloedglukose voorkom. Die teenwoordigheid van **LIZORP** meng nie met die ontleding van plasma- of urienkreatinien met die alkaliese pikraatmetode in nie.

SWANGERSKAP EN LAKTASIE:
Die veiligheid van gebruik is nie in swangerskap en laktasie vasgestel nie (sien "**KONTRA-INDIKASIES**").

DOSIS EN GEBRUIKSAANWYSINGS:
Volwassenes en kinders ouer as 12 jaar:
LIZORP word oraal vir 'n periode van 10 dae in die behandeling van infeksie weens vatbare bakterieë in die volgende toegedien:

Boonste lugweginfeksies:	500 mg elke 24 uur
Benede lugweginfeksies:	500 mg elke 12 uur
Sinusitis:	250 mg elke 12 ure of 500 mg elk 12 ure
Ongekompliseerde urienweginfeksies:	500 mg elke 24 uur
Infeksies van die vel en velstruktuur:	250 mg elke 12 ure of 500 mg elk 12 of 24 ure

Belemmerde nierfunksie
LIZORP mag aan pasiënte met belemmerde nierfunksie toegedien word. Geen dosisaanpassing is nodig vir pasiënte met 'n kreatiniensuiwering van > 30 mℓ/min nie. Vir diegene met 'n kreatiniensuiwering van ≤ 30 mℓ/min, behoort 50 % van die standaarddosis teen die standaard doseringsinterval toegedien te word.
LIZORP word gedeeltelik deur hemodialise verwyder; daarom behoort **LIZORP** na die voltooiing van hemodialise toegedien te word.

Belemmerde lewerfunksie
Geen dosisaanpassing is in pasiënte met belemmerde lewerfunksie nodig nie.

Kinders jonger as 12 jaar oud
Hierdie formulasie is nie geskik vir kinders jonger as 12 jaar oud nie

NEWE EFFEKTE:

Afwykings van die bloed- en limfsisteem:
Baie dikwels: Eosinofilie.
Dikwels: Neutropenie, trombositopenie. Verlengde PT/INR is waargeneem.
Afwykings van die imuunstelsel:
Dikwels: Anafilakse, koors en serumsiekte.
Die volgende newe effekt is aangemeld en die frekwensies is onbekend: Angio-edeem.
Afwykings van die senuweestelsel:
Die volgende newe effekte is aangemeld en die frekwensies is onbekend: Duiseligheid, hiperaktiwiteit, hoofpyn, senuweeagtigheid, slaaploosheid, verwardheid en slaapsug.
Gastroïntestinale afwykings:
Baie dikwels: Naarheid, braking, diarree, pseudomembraneuse kolitis en buikpyn.
Hepatobileêre afwykings:
Dikwels: Cholestatiese geelsug.
Die volgende newe effekte is aangemeld en die frekwensies is onbekend: Verhogings van AST (SGOT), ALT (SGPT), alkaliese fosfataseen en bilirubienwaardes.
Afwykings van die vel en subkutane weefsel:
Dikwels: Erythema multiforme, Stevens-Johnson se sindroom, superinfeksie, uitslag, urtikarie en algemene pruritus.
Nier- en urienafwykings:
Die volgende newe effekte is aangemeld en die frekwensies is onbekend: Verhogings in bloedureum en serumkreatinien.
Reproduksiestelsel- en borsafwykings:
Dikwels: Vaginitis.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
(Sien "**NEWE EFFEKTE**").
In die geval van erge oordosering, veral in pasiënte met belemmerde nierfunksie, sal hemodialise in die verwydering van **LIZORP** uit die liggaam help.

IDENTIFIKASIE:
LIZORP 250 mg:
Oranjegekleurde, bikonvekse filmbedekte kaplette met "C16" met swart ink op die een kant gedruk.
LIZORP 500 mg:
Wit, bikonvekse filmbedekte kaplette met "C17" met swart ink op die een kant gedruk.

AANBIEDING:
1. PVC/ACLAR-Aluminium stolpverpakking:
Tablette word in 250 µm helder PVC film, bedek met 23 µm Aclar as die vormingsmateriaal en 25 µm aluminiumfoelie as die dekmateriaal verpak. Elke stolpverpakking bevat 10 tablette.
Pakgrootte: 10s: Elke karton bevat 1 stolpverpakking met 10 tablette.

2. PVC/PVdc-Aluminium stolpverpakkings:
Tablette word in 250 µm helder PVC film, bedek met 60 g/m^2 PVdc as die vormingsmateriaal en 25 µm aluminiumfoelie as die dekmateriaal verpak. Elke stolpverpakking bevat 10 tablette.
Pakgrootte: 10s: Elke karton bevat 1 stolpverpakking met 10 tablette.

BERGINGSINSTRUKSIES:
Bewaar by of benede 30°C.
HOU BUITE BEREIK VAN KINDERS

REGISTRASIENOMMER:
SUID-AFRIKA:
LIZORP 250 mg: 41/20.1.1/0586
LIZORP 500 mg: 41/20.1.1/0587
NAMIBIË:
LIZORP 250 mg: 10/20.1.1/0246
LIZORP 500 mg: 10/20.1.1/0247

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
Aurogen South Africa (Edms.) Bpk.
Woodhill Kantoorpark, Gebou 1, Eerste vloer
Phillip Engelbrechtlaan 53
Meyersdal, Uitbr. 12
1448 Johannesburg
Suid-Afrika

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5 Desember 2013
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01 Augustus 2021

DETACH BEFORE DISPENSING

SUID AFRIKA: S4

NAMIBIË: NS2

LIZORP 250 mg (tablet)
LIZORP 500 mg (tablet)
Sefprosielmonohidraat.

Lees die hele brosjure sorgvuldig voordat u begin om LIZORP te neem.
- Hou hierdie bladsyje. U mag dit moontlik weer wil lees.
- Indien u enige verdere vrae het, moet u asseblief u dokter of apteker raadpleeg.
- **LIZORP** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense te deel nie. Dit mag hulle skade aandoen, ookal het hulle dieselfde simptome as u.

1. WAT LIZORP BEVAT:
Die aktiewe bestanddeel is sefprosielmonohidraat.
LIZORP 250 mg:
Elke filmbedekte tablet bevat sefprosiel (monohidraat) ekwivalent aan 250 mg anhidriese sefprosiel. Suikervry.
LIZORP 500 mg:
Elke filmbedekte tablet bevat sefprosiel (monohidraat) ekwivalent aan 500 mg anhidriese sefprosiel. Suikervry.

Die ander bestanddele van **LIZORP** is mikrokristallyne sellulose (Avicel PH 102); magnesiumstearaat; natriumstyselglikolaat (Tipe A) en Opadry Oranje YS-1-2456. Die drukmateriaal wat in **LIZORP** gebruik word, is Opacode Swart S-1-17734 en isopropielalkohol.

2. WAARVOOR LIZORP GEBRUIK WORD:
LIZORP is 'n breë-spektrum sefalosporienantibiotika wat gebruik word om die volgende geringe tot matig erge infeksies te behandel:

- Boonste lugweginfeksies – tonsilitis en faringitis.
- Middeloorinfeksie (otitis media).
- Sinusitis.
- Benede lugweginfeksies – brongitis.
- Ongekompliseerde vel- en velstruktuurinfeksies.
- Ongekompliseerde urienweginfeksies.

3. VOORDAT U LIZORP NEEM:
Moenie LIZORP neem nie:

- As u allergies teen sefalosporienantibiotika of enige van die bestanddele van **LIZORP** is.
- Kinders jonger as 1 jaar oud.
- As u swanger is of borsvoed.

Neem spesiale sorg met LIZORP:

- Voordat u begin om **LIZORP** te neem, moet u asseblief u dokter in kennis stel as u enige vorige allergiese reaksies teen **LIZORP**, ander sefalosporienantibiotika, penisillien of ander medisyne gehad het. As u allergies teen penisillien is, behoort u ekstra versigtig te wees aangesien kruissensitiwiteit met **LIZORP** aangemeld is.
- Staak die gebruik van **LIZORP** onmiddellik as u 'n allergiese reaksie ontwikkel en kry nood mediese hulp in die geval van 'n akute reaksie (moeite met asemhaling en/of swelling van die lippe, gesig en keel).
- **LIZORP** kan pseudomembraneuse kolitis veroorsaak. Raadpleeg u dokter as u enige van hierdie simptome ondervind – buikkrampe, bloederige stoelgang, diaree en/of koors.
- Stel u dokter in kennis as u aan 'n niersiekte ly of vantevore aan 'n niersiekte gely het, aangesien u dosis **LIZORP** moontlik aangepas sal moet word.
- As u **LIZORP** vir 'n lang periode van tyd gebruik, kan u 'n superinfeksie opdoen wat beteken dat 'n nuwe infeksie kan voorkom wat weerstandbiedend teen **LIZORP** is. Raadpleeg u dokter as u koors of kouekoors, benede rugpyn of pyn in die sy of pynlike of moeite met urinering ondervind.

Die neem van LIZORP met voedsel:
LIZORP word nie deur voedsel beïnvloed nie en die tablette kan vóór, gedurende of na maaltye geneem word.

Swangerskap en borsvoeding:
Die veiligheid van gebruik gedurende swangerskap en laktasie is nie vasgestel nie.

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander professionele gesondheidsbeampte vir advies soek voordat u hierdie medisyne gebruik.

Bestuur en werk met masjinerie:
LIZORP kan duiseligheid veroorsaak. As u duiselig voel terwyl u **LIZORP** neem, moet u nie bestuur of met gevaarlike gereedskap en masjinerie werk nie.

Die neem van ander medisyne saam met LIZORP:

Stel altyd u professionele gesondheidswerker in kennis as u enige ander medisyne gebruik. (Dit sluit komplementêre en tradisionele medisyne in).

Wanneer u **LIZORP** neem, is dit veral belangrik dat u professionele gesondheidswerker daarvan bewus is as u enige van die volgende neem:

- Ander sefalosporienantibiotika – die gelyktydige gebruik kan die sintese van vitamien K veranderverminder. U sal moontlik profilaktiese vitamien K moet neem as sefalosporienantibiotika vir lang periodes van tyd neem, veral as u ondervoed of ernstig siek is.
- Aminoglikosiedantibiotika – die gelyktydige terapie met sefalosporiene kan u niere beskadig.

Diuretika – die gelyktydige behandeling met sefalosporiene kan u nierfunksie affekteer. As u ander medisyne op 'n gereelde basis neem, insluitende komplementêre en tradisionele medisyne, kan die gebruik van **LIZORP** saam met hierdie medisyne ongewenste interaksies veroorsaak. Raadpleeg asseblief u dokter, apteker of ander professionele gesondheidswerker vir advies.

4. HOE OM LIZORP TE NEEM:

Neem **LIZORP** altyd presies soos deur u dokter voorgeskryf. Bevestig met u dokter of apteker as u onseker is. As u van mening is dat die effek van **LIZORP** te sterk of te swak is, moet u u dokter of apteker raadpleeg.

U dokter sal op grond van u kondisie 'n toepaslike dosis voorskryf.

Volwassenes en kinders ouer as 12 jaar
LIZORP word oraal oor 'n periode van 10 dae toegedien in die behandeling van infeksies wat deur die volgende vatbare bakterieë in die volgende kondisies veroorsaak word:

- Boonste lugweginfeksies: 500 mg elke 24 uur.
- Benede lugweginfeksies: 500 mg elke 12 ure.
- Sinusitis: 250 mg elke 12 ure of 500 mg elke 12 ure.
- Ongekompliseerde urienweginfeksies: 500 mg elke 24 uur.
- Vel- en velstruktuurinfeksies: 250 mg elke 12 ure of 500 mg elke 12 of 24 ure.

Ingekorte nierfunksie
Sefprosiel kan aan pasiënte met ingekorte nierfunksie toegedien word. Geen dosisaanpassing is vir pasiënte met kreatiniensuiweringswaardes van > 30 mℓ/min nodig nie. Vir diegene met kreatiniensuiweringswaardes van ≤ 30 mℓ/min, behoort 50 % van die standaarddosis teen die standaard doseringsinterval toegedien te word.
Sefprosiel word gedeeltelik deur hemodialise verwyder; daarom behoort sefprosiel na die voltooiing van hemodialise toegedien te word.

Ingekorte lewerfunksie
Geen dosisaanpassing is vir pasiënte met ingekorte lewerfunksie nodig nie.

As u te veel LIZORP geneem het:
Simptome van oordosering kan stuipaanvalle, erge buikkrampe en braking insluit.

In die geval van oordosering, raadpleeg u dokter of apteker. As hulle nie beskikbaar is nie, kontak u naaste hospitaal of giftbeheersentrum.

As u vergeet het om LIZORP te neem:
As u vergeet het om 'n dosis van u medisyne te neem, moet u dit neem sodra u daarvan onthou. As dit egter byna tyd vir die volgende dosis is, slaan die oorgeslaande dosis oor en gaan met u oorspronklike dosisskedulering voort. Moenie 'n dubbel dosis neem om vir 'n oorgeslaande op te maak nie

5. MOONTLIKE NEWE EFFEKTE:
LIZORP kan newe effekte hê.
Kry onmiddellik nood mediese hulp as u enige van hierdie tekens van 'n allergiese reaksie toon:

- Anafilakse, gekenmerk deur: Veluitslag, netelroos, moeite met asemhaling, swelling van u gesig, lippe, tong of keel of skok.

Die volgende ernstige newe effekte kan voorkom en vereis mediese aandag:

Baie dikwels:

- Eosinofilie (swart, teeragtige stoelgang, kouekoors, koors, hoes, kortademheid, ongewone moegheid en swakheid).

Dikwels:

- Pseudomembraneuse kolitis (buikkrampe, waterige, erge diaree, koors).

Selde:

- Erythema multiforme of Stevens-Johnson se sindroom (blaasvorming, afskilfering, en loslating van die vel en slymvliese, waarby die oë en ander orgaansisteme betrokke kan wees).
- Neutropenie en trombositopenie (borspyn, kouekoors, koors, ongewone bloeding en kneusing).
- Urtikarie (netelroos of velbulte, jeuk en rooiheid van die vel).
- Serumsiekte (koors, gewrigspyn, velutslag).

Frekwensie onbekend:

- Lewerdisfunksie insluitende cholestase (buik- of maagpyn, kleigekleurde stoelgang, donker urien, hoofpyn, verlies aan eetlus, swakruikende asemhaling).
- Superinfeksie (koors, heesheid of hoes, benede rug- of sypyn, pynlike of moeite met urinering, afname in die hoeveelheid urien.
- Serumsiekte (koors, gewrigspyn, velutslag).

Stel u dokter so gou as moontlik in kennis as enige van die volgende newe effekte waarneem en as enige van hierdie simptome erg of kwellend is, of as hulle nie verdwyn nie.

- Duiseligheid.
- Hiperaktiwiteit.
- Hoofpyn.
- Senuweeagtigheid.
- Slaaploosheid.
- Verwardheid.
- Slaapsug.
- Naarheid.
- Braking, diaree, buikpyn.
- Genitale of vaginale pruritus (jeuk van die vaginale area, pyn gedurende gemeenskap, dik, wit vaginale afskeiding).

Nie al die newe effekte wat vir **LIZORP** aangemeld is, word in hierdie brosjure ingesluit nie. As u algemene gesondheid agteruitgaan of as u enige ongewone effekte ondervind terwyl u **LIZORP** neem, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker om advies raadpleeg.

6. OPBERGING EN WEGDOEN VAN LIZORP:
Berg alle medisyne buite die bereik van kinders.
Bewaar by of benede 30 °C.

Neem alle ongebruikte medisyne na u apteker terug.
Moenie enige ongebruikte medisyne in die drein of riolering (bv. toilette) weggooi nie.

7. AANBIEDING VAN LIZORP:
1. PVC/ACLAR-Aluminium stolpverpakking:
Tablette word in 250 µm helder PVC film, bedek met 23 µm Aclar as die vormingsmateriaal, en 25 µm aluminiumfoelie as die dekmateriaal verpak. Elke stolpverpakking bevat 10 tablette.
Pakgrootte: 10s: Elke karton bevat 1 stolpverpakking met 10 tablette.

2. PVC/PVdc-Aluminium stolpverpakkings:
Tablette word in 250 µm helder PVC film, bedek met 60 g/m^2 PVdc as die vormingsmateriaal, en 25 µm aluminiumfoelie as die dekmateriaal verpak. Elke stolpverpakking bevat 10 tablette.
Pakgrootte: 10s: Elke karton bevat 1 stolpverpakking met 10 tablette.

8. IDENTIFIKASIE VAN LIZORP:
LIZORP 250 mg: Oranjegekleurde, bikonvekse, filmbedekte kaplet met "C16" in swart ink op die een kant gedruk.

LIZORP 500 mg: Wit, bikonvekse, filmbedekte kaplet met "C17" in swart ink op die een kant gedruk.

9. REGISTRASIENOMMER / VERWYSINGSNOMMER:
SUID-AFRIKA:
LIZORP 250 mg: 41/20.1.1/0586
LIZORP 500 mg: 41/20.1.1/0587
NAMIBIË:
LIZORP 250 mg: 10/20.1.1/0246
LIZORP 500 mg: 10/20.1.1/0247

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER
Aurogen South Africa (Edms.) Bpk.
Woodhill Kantoorpark, Gebou 1, Eerste vloer
Phillip Engelbrechtlaan 53
Meyersdal, Uitbr. 12
1448 Johannesburg
Suid-Afrika

11. DATUM VAN PUBLIKASIE
Datum van registrasie:
5 Desember 2013
Datum van hersiening:
01 Augustus 2021

A/s : 280 x 500 mm ■ Black Booklet Size: 40 x 60 mm

AUROBINDO Packaging Development		Product Name	Component	Item Code	Date & Time
		Lizorp Tablets	Leaflet	P1530170	05.02.2022 & 08.40 am
		Country	Version No.	Reason Of Issue	Reviewed / Approved by
		South Africa	02	Commercial	
Team Leader	K. RamGopal	Dimensions (mm)	Colours		
Initiator	Kiran	280 x 500 mm	No Of Colours: 01		
Artist	Sree Designers	Pharma Code: 30170			
Supersede Code: P1513183			30170		

SCHEDULING STATUS

SOUTH AFRICA: S4

NAMIBIA: NS2

PROPRIETARY NAME (and dosage form):
LIZORP 250 mg (tablet)
LIZORP 500 mg (tablet)

COMPOSITION:
LIZORP 250 mg:
Each film-coated tablet contains cefprozil (monohydrate) equivalent to anhydrous cefprozil 250 mg. Sugar free.

LIZORP 500 mg:
Each film-coated tablet contains cefprozil (monohydrate) equivalent to anhydrous cefprozil 500 mg. Sugar free.

The other ingredients of **LIZORP** are cellulose microcrystalline (Avicel PH 102); 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.

PHARMACOLOGICAL CLASSIFICATION:
A 20.1.1 Broad and medium spectrum antibiotics

PHARMACOLOGICAL ACTION:
Cefprozil belongs to a sub-group of beta-lactam antibiotics, cephalosporins (second generation). It is bactericidal and acts by inhibiting synthesis of bacterial cell wall.

Microbiology
Cefprozil has *in vitro* activity against the gram positive and gram negative bacteria *(in vitro* activity does not necessarily imply *in vivo* efficacy).

Resistant Organisms
Aerobes, Gram-positive
Cefprozil is inactive against methicillin-resistant staphylococci and *Enterococcus faecium.*

Aerobes, Gram-negative
Cefprozil is inactive against most strains of *Acinetobacter, Enterobacter, Morganella morganii, Proteus vulgaris, Providencia, Pseudomonas* and *Serratia.*

Anaerobes
NOTE: Most strains of the *Bacteroides fragilis* group are resistant to cefprozil.

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/tonsilitis caused by *Streptococcus pyogenes.*
NOTE: 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 and sinusitis
Otitis media and sinusitis caused by *Streptococcus pneumoniae, Haemophilus influenzae* and *Branhamella catarrhalis.*
NOTE: 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 pneumonia, Haemophilus influenza* (beta-lactamase positive and negative strains) and *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.*
NOTE: 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 with known allergy to the cephalosporin class of antibiotics as well as other beta-lactam group of antibiotics, e.g. penicillin, or any component of the formulation (see **"WARNINGS AND SPECIAL PRECAUTIONS"**).
- 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 this product 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 the medication. Serious acute hypersensitivity reactions may require emergency treatment measures.

Paediatric use
Safety and effectiveness 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.

Pseudomembranous colitis has been reported with the use of **LIZORP**. Symptoms of pseudomembranous colitis include severe, persistent diarrhoea, severe abdominal cramps as well as bloody stools. Extreme caution must be practiced in patients using **LIZORP** who have a history of gastrointestinal diseases. Patients experiencing extreme diarrhoea while taking **LIZORP** must discontinue treatment immediately and seek emergency medical advice.

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 such as **LIZORP**.

LIZORP contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp Lactase deficiency or glucose-galactose malabsorption should not take **LIZORP**.

Effects on ability to drive and use machinery:
The potential for dizziness should be taken into account before patients on **LIZORP** drive or use machinery.

INTERACTIONS:
LIZORP can inhibit vitamin K synthesis by suppressing gut flora which may increase the risk of bleeding. In addition, there have been reports of prothrombin times being increased in patients taking **LIZORP** tablets and warfarin, in particular. Dosage adjustment of anti-coagulant medicine may be necessary pre- and post-treatment with **LIZORP** tablets.

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 (see **"CONTRA-INDICATIONS"**).

DOSAGE AND DIRECTIONS FOR USE:

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

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.

Children less than 12 years old
This formulation is not suitable for children less than 12 years old.

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 and serum sickness.
The following side effect has been reported and frequencies are 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, pseudomembranous colitis and abdominal pain.

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

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

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: Vaginitis.

KNOWN SYMPTOMS OF OVER DOSAGE 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 250 mg:
Orange coloured, biconvex, film-coated caplets imprinted "C16" with black ink on one side.

LIZORP 500 mg:
White, biconvex, film-coated caplets imprinted "C17" with black ink on one side.

PRESENTATION
1. PVC/ACLAR-Aluminium blister packs:
Tablets are packed in 250 µm clear PVC film laminated with 23 µm Aclar as the forming material and aluminium foil 25 µm as the lidding material. Each blister contains 10 tablets.
Pack size: 10s: Each carton contains 1 blister of 10 tablets.

2. PVC/PVdc-Aluminium blister packs:
Tablets are packed in clear 250 µm PVC coated with 60 g/m^2 PVdc as the forming material and aluminium foil 25 µm as the lidding material. Each blister contains 10 tablets.
Pack size: 10s: Each carton contains 1 blister of 10 tablets.

STORAGE INSTRUCTIONS:
Store at or below 30 ºC.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
SOUTH AFRICA:
LIZORP 250 mg: 41/20.1.1/0586
LIZORP 500 mg: 41/20.1.1/0587
NAMIBIA:
LIZORP 250 mg: 10/20.1.1/0246
LIZORP 500 mg: 10/20.1.1/0247

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 December 2013

Date of revision:
01 August 2021

P1530170

DETACH BEFORE DISPENSING

SOUTH AFRICA: S4

NAMIBIA: NS2

LIZORP 250 mg (tablet)
LIZORP 500 mg (tablet)
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** 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.

1. WHAT LIZORP CONTAINS:
The active ingredient is cefprozil monohydrate.

LIZORP 250 mg:
Each film-coated tablet contains cefprozil (monohydrate) equivalent to anhydrous cefprozil 250 mg. Sugar free.

LIZORP 500 mg:
Each film-coated tablet contains cefprozil (monohydrate) equivalent to anhydrous cefprozil 500 mg. Sugar free.

The other ingredients of **LIZORP** are cellulose microcrystalline (Avicel PH 102); 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 cephalosporin 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 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 tablets may be taken before, during or after meals.

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

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

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.

Taking other medicines with LIZORP:

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

When you are taking **LIZORP**, it is especially important that your healthcare professional knows if you are taking any of the following:
- Other cephalosporin antibiotic – 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. 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 your condition.

Adults and children over 12 years
LIZORP are 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

Kidney Impairment
Cefprozil may be administered to patients with impaired kidney 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. Cefprozil is in part removed by haemodialysis; therefore, cefprozil should be administered after the completion of haemodialysis.

Liver Impairment
No dosage adjustment is necessary for patients with impaired liver function.

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, contact 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.
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:
Frequent
- Eosinophilia (black, tarry stools, chills, fever, cough, shortness of breath, unusual tiredness and weakness).

Less frequent
- Pseudomembranous colitis (abdominal cramps, watery, severe diarrhoea, fever).

Rare
- Erythema multiforme or Stevens-Johnsons syndrome (blistering, peeling, loosening of skin and mucous membranes, which may involve the eyes or other organ systems)
- Neutropenia or thrombocytopenia (chest pain, chills, fever, unusual bleeding and bruising).
- Urticaria (hives or wells, itching and redness of skin).
- Serum sickness (fever, joint pain, skin rash).

Frequency unknown
- 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 healthcare professional for advice.

6. STORING AND DISPOSING OF LIZORP:
Store all medicines out of the reach of children
Store at or below 30 °C.

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 µm clear PVC film laminated with 23 µm Aclar as the forming material and aluminium foil 25 µm as the lidding material. Each blister contains 10 tablets.
Pack size: 10s: Each carton contains 1 blister of 10 tablets.

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9. REGISTRATION NUMBER / REFERENCE NUMBER:
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10. 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

11. DATE OF PUBLICATION:
Date of registration:
5 December 2013

Date of revision:
01 August 2021