Front Top

340 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LOZPRAS 15 MG CAPSULES
Each delayed release capsule contains Lansoprazole 15 mg
Contains sugar (82,2 mg of sucrose).

LOZPRAS 30 MG CAPSULES
Each delayed release capsule contains Lansoprazole 30 mg.
Contains sugar (165,0 mg of sucrose).

Read all of this leaflet carefully before you start taking LOZPRAS
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **LOZPRAS** 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.

What is in this leaflet

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

1. What LOZPRAS is and what it is used for

- **LOZPRAS** is used to treat certain conditions in which there is too much acid in the stomach and to reduce the amount of acid your stomach makes.

- **LOZPRAS** is used in the short-term to:
  - Treat ulcers in your stomach or duodenum.
  - Heal your oesophagus (gullet) if it has become damaged or inflamed. This is called gastro-oesophageal reflux disease (GORD).
  - Stop these conditions from coming back.
  - To manage heartburn or indigestion.
  - Sometimes **LOZPRAS** is used in combination with antibiotics to treat ulcers associated with infection caused by the *H. pylori* bacteria (germ).

2. What you need to know before you take LOZPRAS

Do not take **LOZPRAS** if:
- you are allergic to lansoprazole or any of the ingredients of lansoprazole capsules.
- you are pregnant or trying to become pregnant or are breastfeeding.
- you have any liver problems.
- You are taking other medicines such as
  - atazanavir and nelfinavir - used to treat HIV

Warnings and precautions
LOZPRAS
Take special care by telling your doctor:
- If you have serious liver disease. The doctor may have to adjust your dosage.
- If you think you have signs of stomach cancer. These include persistent weight loss, dark stools, loss of appetite, feeling full or a lump in your stomach.
- may affect the kidneys (interstitial nephritis). Inform your doctor if you experience any pain while urinating or lower back pain.
- If you are taking vitamin B12, vitamin C or calcium supplements
- If you have been previously treated with another proton pump inhibitor and have experienced skin lesions or reactions.
- If you drink alcohol or are on any anti-depressants
- If you are on **LOZPRAS** for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium
- Taking a proton pump inhibitor like **LOZPRAS**, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).
- If you have other chronic medical conditions and are taking other antibiotics
- Long term treatment may cause stomach glandular cysts
- If you experience severe and/or persistent diarrhoea, as **LOZPRAS** has been associated with a small increase in infectious diarrhoea.
- If you are experiencing weight loss, vomiting, inability to eat, blood in the vomit or stool as malignancy (cancer) should be excluded since treatment with **LOZPRAS** may relieve/mask symptoms thereby delaying diagnosis.
- If your doctor has given you **LOZPRAS** in addition to other medicines intended for the treatment of Helicobacter pylori infection (antibiotics) or together with anti-inflammatory medicines to treat your pain or rheumatic disease: please also read the package leaflets of these medicines carefully
- If you take **LOZPRAS** on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Other medicines and LOZPRAS
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
In particular tell your doctor or pharmacist if you are taking medicines containing any of the following active substances as **LOZPRAS** may affect the way these medicines work:
- HIV protease inhibitors such as atazanavir and nelfinavir (used to treat HIV)
- ketoconazole, itraconazole, rifampicin (used to treat infections)
- digoxin (used to treat heart problems)
- theophylline (used to treat asthma)
- tacrolimus (used to prevent transplant rejection)
- fluvoxamine (used to treat depression and other psychiatric diseases)
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)
- warfarin (used to treat blood clots)
- antacids (used to treat heartburn or acid regurgitation)
- methotrexate (used to treat autoimmune disease and cancer)
- sucralfate (used for healing ulcers)

Ask your doctor or pharmacist if you are not sure whether your other medicines contain any of the above substances.

LOZPRAS with food and drink:
LOZPRAS should preferably be taken before a meal. Taking alcohol with **LOZPRAS** may lead to drowsiness and impaired concentration.

Pregnancy, breastfeeding and fertility
LOZPRAS must not be taken if you are pregnant or if you are breastfeeding your baby (see above, Do not take **LOZPRAS**)

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

LOZPRAS
15 mg / 30 mg
Capsules
PM04003802

Driving and using machines
Side effects such as dizziness, vertigo, tiredness and visual disturbances sometimes occur in patients taking lansoprazole capsules. If you experience side effects like these you should take caution as your ability to react may be decreased.
You alone are responsible to decide if you are in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration.

LOZPRAS contains sucrose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **LOZPRAS.**

3. How to take LOZPRAS

Do not share medicines prescribed for you with any other person.
Always take **LOZPRAS** exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are not sure.
Take **LOZPRAS** by mouth.
The recommended once daily dosage should preferably be taken before a meal.
The usual dose is one 30 mg capsule once a day for up to eight weeks.

Duodenal ulcer:
One 30 mg capsule per day for 2-4 weeks. Patients may respond adequately to 15 mg daily for 2-4 weeks, and therefore individual dose adjustment should be considered.

Oesophagitis due to gastro-oesophageal reflux:
One 30 mg capsule per day for 4 weeks with a second 4-week treatment period, at the same dosage, depending on endoscopic results.

Maintenance treatment for the prevention of gastro-oesophageal reflux:
One 15 mg capsule per day for up to one year.

Functional dyspepsia:
One 15 mg capsule daily for 2-4 weeks.

Children:
Lansoprazole should not be used in children

If you take more LOZPRAS than you should
In the event of an overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take LOZPRAS:
If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten doses.

If you stop taking LOZPRAS:
Do not stop taking **LOZPRAS** just because you feel better. It is important that you carry on taking **LOZPRAS** for as long as your doctor tells you.

4. Possible side effects

LOZPRAS can have side effects.

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

If any of the following happens, stop taking LOZPRAS and tell your doctor immediately or go to the casualty department at your nearest hospital.
- Shortness of breath, face swelling or another symptom of a serious allergic reaction
- Skin rash or itching
- Reddening or blistering of your skin

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Chest pain
- Angina
- Changes in the way your heart beats
- Difficulty breathing

These are all serious side-effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects may include:
- Headache, dizziness
- Diarrhea, nausea, vomiting, constipation, stomach pain, flatulence or gas, dry mouth or throat
- Increase in liver enzymes
- Skin rash and itching
- Tiredness

Less frequent side effects
- Fungal infection and flu-like infection
- Throat, skin and stomach cancers
- a reduction in the number of white blood cells (which may lead to frequent infections) or red blood cells.
- Hypersensitivity or allergic reactions
- Inability to eat, increased uric acid in the blood, dehydration, increased or decreased sugar levels, swelling, weight gain or loss, decreased magnesium levels which causes cramping.
- Problems with sleeping, depression, hallucinations, feeling nervous, abnormality in thinking, mood or mental changes
- Shakes, abnormal dreams, fits, double-vision, "pins and needles", dizziness, restlessness, forgetfulness, paralysis of one side of the body, muscle spasms
- Vision disturbances (blurred vision), abnormal vision, "pink eye", dry eyes, eye pain, and light sensitivity
- Inability to hear, ear infections, ringing in the ears
- Chest pain, abnormal heartbeat, heart attack, fast heart beat
- Swelling, stroke, high or low blood pressure, shock, fainting
- Asthma, chest and throat infection, cough, inability to breath, hiccups, nose-bleeds
- Inability to taste, bad breath, stool discoloration, inflammation in the gut, vomiting blood, bleeding gums, increased appetite, increased production of saliva, blood in the stool
- liver injury causing jaundice (yellowing), inflammation of the liver
- hair loss, acne, dry skin, rash, increased sweating, blistering, loosening, peeling or redness of the skin, skin rash, hives or itching
- joint and muscle pain, back pain, chills, stiff neck, arthritis, bone disorders, fractures of the hip, wrist or spine
- kidney problems, bladder infection, urgent need to urinate, passing excessive amounts of urine
- pelvic pain, increased or decreased libido, menstrual abnormalities, increase in breast size, breast pain and tenderness, impotence, vaginal white-yellow discharge, milk-like discharge from the nipple
- fever, tiredness, pain, abnormal physical weakness
- increase in cholesterol levels, decrease in sodium levels

Frequency unknown
- Collagenous colitis - a type of microscopic colitis (inflammation of the inner lining of the colon) that causes periods of watery, non-bloody diarrhoea that can last for days to months.
- Cysts in the stomach

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**", found online under SAHPRA's publications:https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **LOZPRAS.**

5. How to store LOZPRAS

Store at or below 25 °C (room temperature). Protect from light.
Keep the blisters in the carton until required for use.
Keep the HDPE container tightly closed.
Store in the original package in order to protect from light and moisture.
KEEP OUT OF THE REACH OF CHILDREN.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister /label/carton/bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What LOZPRAS contains
LOZPRAS 15 MG CAPSULES
Each **LOZPRAS 15 MG CAPSULES** contains lansoprazole 15 mg.
Contains sugar (82,2 mg of sucrose).

LOZPRAS 30 MG CAPSULES
Each **LOZPRAS 30 MG CAPSULES** contains lansoprazole 30 mg.
Contains sugar (165,0mg of sucrose).

Other ingredients include:
Excipients: Sugar spheres (20 - 25 mesh ASTM), Ethyl cellulose, Hypromellose 2910 (Methocel E5 premium LV), Methylene chloride, Isopropyl alcohol, Magnesium carbonate heavy, Low substituted hydroxypropyl cellulose (LH 31), Maize starch, Talc, Polyethylene glycol (Polyglycol 6000 PF), Methacrylic acid copolymer dispersion (Eudragit L 30D 55, Titanium dioxide (Kronos 1171), Polysorbate 80 Tween 80 HP-LQ-(MH) and Colloidal silicon dioxide (Aerosil 200)

Composition of Inactive Ingredients (Capsule):
Cap: Gelatin, Water, FD & C Blue 1 (E 133), D & C Red 28, FD & C Red 40 (E 129), Titanium Dioxide (E 171).
Body:
For 15 mg: Gelatin, Water, Titanium Dioxide (E171) and FD & C Green 3 (E143).
For 30 mg: Gelatin, Water, Titanium Dioxide (E171), FD & C Blue 1 (E133) and FD & C Red 40 (E129).

What LOZPRAS look like and contents of the pack
LOZPRAS 15 MG CAPSULES
Opaque pink cap/ Opaque green body Size "3" capsule containing white-off white to dark brown delayed release pellets with 'C86' on cap and '15 mg' on body imprinted with white ink.

LOZPRAS 30 MG CAPSULES
Opaque pink cap/ Opaque black body Size "1" capsule containing white-off white to dark brown delayed release pellets with 'C85' on cap and '30 mg' on body imprinted with white ink.

HDPE Container Pack (28's and 30's):
Round, white, HDPE container, 60cc, 33 mm screw neck, with 33 mm closure with pulp and HS 123 white printed liner and silica gel sachet 1g (2 Nos.) as a desiccant.

Blister pack 2's, 4's, 7s ,14's, 28's and 30's:
Cold form laminate as forming material: 25µ OPA/ 45µ Aluminium / 60 µ PVC and Aluminium foil as liddingmaterial:Plain 30 µ Aluminum Foil/ 6 - 8 gsm HSL
Not all pack sizes are necessarily marketed.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

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Registration number
LOZPRAS 15 MG CAPSULES: 52/11.4.3/0362.358
LOZPRAS 30 MG CAPSULES: 52/11.4.3/0363.359

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://macleodssaproducts.co.za/ or contact 011 682 1169

335 mm

Back Top

340 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS S4

LOZPRAS 15 MG CAPSULES
Elke vertraagde vrystelling kapsule bevat Lansoprasool 15 mg
Bevat suiker (82,2 mg van sukrose)

LOZPRAS 30 MG CAPSULES
Elke vertraagde vrystelling kapsule bevat Lansoprasool 30 mg
Bevat suiker (165,0 mg van sukrose)

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy LOZPRAS begin neem:
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het
- **LOZPRAS** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat in hierdie inligtingstuk is

1. Wat **LOZPRAS** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **LOZPRAS** neem
3. Hoe om **LOZPRAS** te neem
4. Moontlike newe-effekte
5. Hoe om **LOZPRAS** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat LOZPRAS is en waarvoor dit gebruik word

- **LOZPRAS** word gebruik om sekere toestande, waar daar te veel suur in die maag is, te behandel en om die hoeveelheid suur wat jou maag maak te verminder.

- **LOZPRAS** word op kort termyn gebruik om:
  - Maagsere in jou maag of duodenum te behandel.
  - Jou esofagus (slukderm) te genees as dit beskadig of ontsteek is. Dit word gastro-esofageale refluks siekte (GORD) genoem.
  - Hierdie toestande te stop om terug te kom.
  - Sooibrand of spysvertering te beheer.
  - Soms word **LOZPRAS** in kombinasie met antibiotika gebruik om maagsere wat geassosieer is met infeksie wat veroorsaak word deur die *H. Pylori* bakterieë ('n kiem), te behandel.

2. Wat jy behoort te weet voordat jy LOZPRAS neem

Moet nie **LOZPRAS** neem nie indien:
- jy allergies vir lansoprasool of vir enige van die bestanddele van lansoprasool kapsules is
- jy swanger is of probeer om swanger te raak, of borsvoed.
- jy enige lewerprobleme het.
- jy ander medisyne neem soos
  - atasanavir en nelfinavir – gebruik om MIV te behandel

Waarskuwings en voorsorgmaatreëls
LOZPRAS
Neem spesiale sorg deur jou dokter te vertel:
- Indien jy ernstige lewer siekte het. Die dokter sal dalk jou dosis moet aanpas.
- Indien jy vermoed dat jy tekens van maagkanker het. Dit sluit aanhoudende gewigsverlies, donker stoelgang, verlies aan eetlus, versadigde gevoel of 'n knop in jou maag in.
- kan die niere aantas (interstisiële nefritis). Stel jou dokter in kennis as jy enige pyn ervaar terwyl jy urineer, of van lae rug pyn.
- Indien jy vitamien B12, vitamien C of kalsiumaanvullings neem
- Indien jy voorheen met 'n ander protonpompinhibeerder behandel is en velletsels of reaksies ervaar het.
- Indien jy alkohol drink of enige antidepressante gebruik
- Indien jy vir meer as drie maande op **LOZPRAS** is, is dit moontlik dat die vlakke van magnesium in jou bloed kan daal. Lae vlakke van magnesium kan gesien word as moegheid, onwillekeurige spiersametrekkings, disoriëntasie, stuiptrekkings, duiseligheid, verhoogde harttempo. Indien jy enige van hierdie simptome kry, vertel asseblief onmiddellik jou dokter. Lae vlakke van magnesium kan ook lei tot 'n afname in kalium- of kalsiumvlakke in die bloed. Jou dokter kan besluit om gereelde bloedtoetse uit te voer om jou vlakke van magnesium te monitor.
- Die neem van 'n protonpompinhibeerder soos **LOZPRAS,**veral oor 'n tydperk van meer as een jaar, kan jou risiko van fraktuur in die heup, pols of ruggraat effens verhoog. Vertel jou dokter as jy osteoporose het of as jy kortikosteroïede gebruik (wat die risiko van osteoporose kan verhoog).
- Indien jy ander chroniese mediese toestande het en ander antibiotika neem
- Langtermynbehandeling kan maagkliersiste veroorsaak
- Indien jy ernstige en/of aanhoudende diarree ervaar, aangesien **LOZPRAS** met 'n klein toename in aansteeklike diaree geassosieer is.
- Indien jy gewigsverlies, braking, onvermoë om te eet, bloed in die breaksel of stoelgang ervaar, aangesien maligniteit (kanker) uitgesluit moet word, omdat behandeling met **LOZPRAS** simptome kan verlig/maskeer en sodoende diagnose kan vertraag.
- Indien jou dokter vir jou **LOZPRAS** gegee het, bykomend tot ander medisyne wat bedoel is vir die behandeling van *Helicobacter pylori* infeksie (antibiotika), of saam met anti-inflammatoriese medisyne om jou pyn of rumatiese siekte te behandel: lees asseblief ook die inligtingstukke van hierdie medisyne sorgvuldig.
- Indien jy **LOZPRAS** op 'n langtermynbasis (langer as 1 jaar) neem, sal jou dokter jou waarskynlik onder gereelde toesig hou. Jy moet enige nuwe en buitengewone simptome en omstandighede aanmeld, wanneer jy jou dokter sien.

Ander medisyne en LOZPRAS
Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in).
Vertel varal jou dokter of apteker indien jy medisyne gebruik wat enige van die volgende aktiewe bestanddele bevat, aangesien **LOZPRAS** die manier waarop hierdie medisyne werk, kan beïnvloed:
- MIV protease inhibeerders soos atasanavir en nelfinavir (gebruik om MIV te behandel)
- ketokonasool, itrakonasool, itfamplsien (gebruik om infeksies te behandel)
- digoksien (gebruik om hartprobleme te behandel)
- teofillien (gebruik om asma te behandel)
- takrolimus (gebruik om oorplantings verwerping te voorkom)
- fluvoksamien (gebruik om depressie en ander psigiatriese siektes te behandel)
- Sint Johanneskruid (*Hypericum perforatum*) (gebruik om ligte depressie te behandel)
- warfarien (gebruik om bloedklonte te behandel)
- teensuurmiddels (gebruik vir die behandeling van sooibrand of suurterugkering)
- metotreksaat (gebruik om outo-immuun siektes en kanker te behandel)
- sukralfaat (gebruik vir die genesing van maagsere)

Vra jou dokter of apteker indien jy nie seker is of jou ander medisyne enige van die bogenoemde bestanddele bevat nie.

LOZPRAS met kos en vloeistof:
LOZPRAS moet verkieslik voor 'n ete geneem word. Die neem van alkohol saam met **LOZPRAS** kan lei tot lomerigheid en verswakte konsentrasie.

Swangerskap, borsvoeding en fertiliteit
LOZPRAS moet nie geneem word as jy swanger is of as jy jou baba borsvoed nie (sien hierbo, Moet nie **LOZPRAS** neem nie).

Indien jy swanger is of borsvoed, vermoed dat jy dalk swanger is, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne gebruik.

Bestuur en gebruik van masjinerie
Newe-effekte soos duiseligheid, vertigo, moegheid en visuele versteurings kom soms voor in pasiënte wat lansoprasool kapsules neem. Indien jy newe-effekte soos hierdie ervaar, moet jy versigtig wees aangesien jou vermoë om te reageer kan afneem.
Jy alleen is verantwoordelik om te besluit of jy in 'n geskikte toestand is om 'n motorvoertuig te bestuur of ander take te verrig wat verhoogde konsentrasie verg.

LOZPRAS bevat sukrose.
Indien jou dokter vir jou gesê het dat jy 'n onverdraagsaamheid teenoor sekere sukkers het, kontak jou dokter voordat jy **LOZPRAS** neem.

3. Hoe om LOZPRAS te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **LOZPRAS** presies soos jou dokter of apteker jou beveel het. Jy moet jou dokter of apteker raadpleeg indien jy nie seker is nie.
Neem **LOZPRAS** per mond.
Die aanbevole een maal per dag dosering moet verkieslik voor ete geneem word.
Die gewone dosis is een 30 mg kapsule een keer per dag vir tot agt weke.
Duodenale ulkus:
Een 30 mg kapsule per dag vir 2-4 weke. Pasiënte kan voldoende reageer op 15 mg per dag vir 2-4 weke, en daarom moet individuele dosisaanpassing oorweeg word.

Esofagitis as gevolg van gastroësofegeale refluks:
Een 30 mg kapsule per dag vir 4 weke met 'n tweede behandelingsperiode van 4 weke, teen dieselfde dosis, afhangend van endoskopiese resultate.

Onderhoudsbehandeling vir die voorkoming van gastroësofageale refluks:
Een 15 mg kapsule per dag vir tot een jaar.

Funksionele dispepsie:
Een 15 mg kapsule per dag vir 2-4 weke.

Kinders:
Lansoprasool moet nie in kinders gebruik word nie.

Indien jy meer LOZPRAS neem as wat jy behoort te neem
In die geval van 'n oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om LOZPRAS te neem
Indien jy 'n dosis van hierdie medisyne oorslaan, neem dit so gou as moontlik. As dit egter amper tyd is vir jou volgende dosering, slaan die oorgeslane dosis oor en gaan terug na jou gewone doseringskedule. Moet nie 'n dubbele dosering neem om vir vergete dosisse op te maak nie.

Indien jy ophou om LOZPRAS te neem:
Moet nie ophou om **LOZPRAS** te neem net omdat jy beter voel nie. Dit is belangrik dat jy aanhou om **LOZPRAS** te neem vir so lank as wat jou dokter jou voorskryf om dit te doen.

4. Moontlike newe-effekte

LOZPRAS kan newe-effekte hê.
Nie al die newe-effekte wat vir LOZPRAS aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verslag of indien jy enige ongewenste effekte ondervind terwyl jy hierdie medisyne neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, staak die gebruik van LOZPRAS en lig onmiddellik jou dokter in, of gaan na die ongevalle afdeling van jou naaste hospitaal:
- Kort van asem, gesigswelling of 'n ander simptoom van 'n ernstige allergiese reaksie
- Veluitslag of jeuk
- Rooiheid of blase van jou vel

Hierdie is alles baie ernstige newe-effekte. Indien jy dit het, het jy moontlik 'n ernstige reaksie op **LOZPRAS** gehad. Jy het moontlik dringende mediese aandag of hospitalisasie nodig.

Vertel onmiddellik jou dokter of gaan na die ongevalle afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:
- Borskaspyn
- Angina
- Verandering in die manier waarop jou hart klop
- Moeilike asemhaling

Hierdie is alles ernstige newe-effekte. Jy het moontlik dringende mediese aandag nodig.

Vertel jou dokter indien jy enige van die volgende opmerk:

Gereelde newe-effekte kan insluit:
- Hoofpyn, duiseligheid
- Diaree, naarheid, braking, hardlywigheid, maagpyn, winderigheid of winde, droë mond of keel
- Toename in lewerensieme
- Veluitslag en jeuk
- Moegheid

Minder gereelde newe-effekte:
- Sweminfeksie en griepagtige infeksie
- Keel-, vel- en maagkanker
- 'n Vermindering in die aantal witbloedselle (wat tot gereelde infeksies kan lei) of rooibloedselle
- Hipersensitiwiteit of allergiese reaksies
- Onvermoë om te eet, verhoogde uriensuur in die bloed, dehidrasie, verhoogde of verlaagde suikervlakke, swelling, gewigstoename of -verlies, verlaagde magnesiumvlakke wat krampe veroorsaak.
- Probleme met slaap, depressie, hallusinasies, senuweeagtige gevoel, abnormaliteit in denke, bui of geestelike veranderinge
- Bewing, abnormale drome, aanvalle, dubbelvisie, "speldе en naalde", duiseligheid, rusteloosheid, vergeetagtigheid, verlamming van die een kant van die liggaam, spierspasmas
- Visleversteurings (dowwe visie), abnormale visie, "pienk oë", droë oë, oogpyn en ligsensitiwiteit,
- Onvermoë om te hoor, oorinfeksies, suising in die ore
- Borskaspyn, abnormale hartklop, hartaanval, vinnige hartklop
- Swelling, bevoerte, hoë of lae bloeddruk, skok, floute
- Asma, bors- en keelinfeksie, hoes, onvermoë om asem te haal, hik, neusbloedings
- Onvermoë om te proe, slegte asem, verkleuring van stoelgang, ontsteking in die ingewande, braking van bloed, bloeiende tandvleise, verhoogde eetlus, verhoogde produksie van speeksel, bloed in die stoelgang
- lewerbesering wat geelsug (vergeling) veroorsaak, inflammasie van die lewer
- haarverlies, aknee, droë vel, uitslag, verhoogde sweet, blase, loslating, afskilfering of rooiheid van die vel, veluitslag, galbulte of jeuk
- gewrig- en spierpyn, rugpyn, kouekoors, stywe nek, artritis, beenafwykings, frakture van die heup, pols of ruggraat
- nierprobleme, blaasinfeksie, dringende behoefte om te urineer, passeer oormatige hoeveelhede uriene
- bekkenpyn, verhoogde of verminderde libido, menstruele abnormaliteite, toename in borsgrootte, borspyn en -teerheid, impotensie, vaginale wit-geel afskeiding, melkagtige afskeiding vanuit die tepel
- koors, moegheid, pyn, abnormale fisiese swakheid
- toename in cholesterolvlakke, afname in natriumvlakke

Frekwensie onbekend
- Kollageneuse kolitis - 'n tipe mikroskopiese kolitis (ontsteking van die binne voering van die kolon) wat periodes van waterige, nie-bloederige diaree kan veroorsaak wat vir dae tot maande kan duur.
- Siste in die maag

Lig asseblief jou dokter of apteker in indien jy enige newe-effekte waarneem wat nie in hierdie inligtingstuk genoem word nie.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **"6.04 Adverse Drug Reaction & Quality Problem Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van **LOZPRAS** te verskaf.

5. Hoe om LOZPRAS te bewaar

Bewaar by of benede 25 °C (kamertemperatuur). Beskerm teen lig.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Hou die HDPE houer dig toe.
Stoor in die oorspronklike verpakking om sodoende teen lig en vog te beskerm.
BEWAAR BUITE DIE BEREIK VAN KINDERS.
Moet nie in 'n badkamer bêre nie.
Moet nie na die vervaldatum, wat aangebring is op die stulpstrook/etiket/karton/bottel, gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die verpakking en ander inligting

Wat LOZPRAS bevat
LOZPRAS 15 MG CAPSULES
Elke **LOZPRAS 15 MG CAPSULES** bevat lansoprasool 15 mg.
Bevat suiker (82,2 mg sukrose).

LOZPRAS 30 MG CAPSULES
Elke **LOZPRAS 30 MG CAPSULES** bevat lansoprasool 30 mg.
Bevat suiker (165,0 mg sukrose).

Ander bestanddele sluit in:
Hulpstowwe: Suikersfere (20 - 25 maas ASTM), Etielsellulose, Hipromellose 2910 (Methocel E5 premium LV), Metlleenchloried, Isopropielalkohol, swaar Magnesiumkarbonaat, Lae-gesubstitueerde hidroksipropielsellulose (LH 31), Mieliestysel, Talk, Poliëtileenglikol (Poliglikol 8 000 PF), Metakrielsuur-kopolimeerdispersie (Eudragit L 30D 55, Titaandioksied (Kronos 1171), Polisorbeat 80 Tween 80 HP- LQ- (MH)
Kolloïdale silikondioksied (Aerosil 200)

Samestelling van onaktiewe bestanddele (kapsule):
Dop: Gelatien, Water, FD & C Blou 1 (E 133), D & C Rooi 28, FD & C Rooi 40 (E 129), Titaandioksied (E 171)
Liggaam:
Vir 15 mg: Gelatien, Water, Titaandioksied (E171) en FD & C Groen 3 (E143)
Vir 30 mg: Gelatien, Water, Titaandioksied (E171), FD & C Blue 1 (E133) en FD & C Rooi 40 (E129).

Hoe LOZPRAS lyk en inhoud van die verpakking

LOZPRAS 15 mg
Ondeursigtige pienk dopple/ Ondeursigtige groen lyf, Grootte "3" kapsule wat wit tot naaswit tot donkerbruin vertraagde vrystelling korrels bevat met 'C86' op die dopple en '15 mg' op die lyf bedruk met wit ink.

LOZPRAS 30 mg
Ondeursigtige pienk dopple/ Ondeursigtige swart lyf, Grootte "1" kapsule wat wit tot naaswit tot donkerbruin vertraagde vrystelling korrels bevat met 'C85' op die dopple en '30 mg' op die lyf bedruk met wit ink.

HDPE houer verpakking (28's en 30's):
Ronde, wit, HDPE houer, 60cc, 33 mm skroefnek, met 33 mm sluiting met pulp en HS 123 wit gedrukte voering en silikagel sakkie 1g (2 Nos.) as 'n droogmiddel.

Stulpverpakking 2's, 4's, 7's, 14's, 28's en 30's
Koue vorm laminaat as vormingsmateriaal: 25µ OPA/ 45µ Aluminium / 60µ PVC en Aluminiumfoelie as dekmateriaal: Gewone 30 µ Aluminiumfoelie/ 6 - 8 gsm HSL
Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die Sertifikaat van Registrasie en Vervaardiger
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Weg 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid Afrika

Hierdie inligtingstuk was hersien in
13 SEPTEMBER 2022

Registrasienommers
LOZPRAS 15 MG CAPSULES: 52/11.4.3/0362.358
LOZPRAS 30 MG CAPSULES: 52/11.4.3/0363.359

Vir die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan by https://macleodssaproducts.co.za/ verkry word of deur 011 682 1169 te kontak

335 mm

MASTER COPY

MACLEODS

Restricted Circulation

PACKAGING RESEARCH & DEVELOPMENT

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Exclude Professional Information & dimensions change.

1. Product: LOZPRAS 15/30 MG CAPSULES (Lansoprazole Delayed -Release Capsule 15/30 mg)					
2. Country: South Africa - Private Market		3. Packaging component: Patient Information Leaflet			
4. No. of Colours: 1 Colour		5. Pantone Shade No.: Black			
6. Specification: 40 GSM Bible paper					
7. Machine Layout No.: NA		8. Dimensions: 340 (L) x 335 (W) mm			
9. Design / Style: Booklet		10. Item code No.: PM04003802			
11. Artwork has been made: Actual Size		12. Pharma code No.: 33135 mini			
13. Barcode/NDC no: NA		14. Supersedes Item code No: PM04003801			
15. Revision no: 01		16. A/W File name:X:\Lansoprazole\SA Private Market\02\Lansoprazole DR Capsule leaflet - PM04003802.cdr			
Approved By:		17. Location: Baddi			
PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
28/07/2023	Vanita Rajool	01/08/23	18/08/23	14/8/23	19/08/23

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

QA 19/08/23

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa Private Market	PM04003801	08/12/22	Not Implemented
2) Exclude Professional Information & dimensions change.	PM04003802		

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