PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

RAN-LANSOPRAZOLE 15 capsules/

RAN-LANSOPRAZOLE 30 capsules

Contains sugar (sucrose)

Each 15 mg capsule contains sucrose 80 mg.

Each 30 mg capsule contains sucrose 160 mg.

Read all of this leaflet carefully before you start taking RAN- LANSOPRAZOLE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- RAN-LANSOPRAZOLE 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.

What is in this leaflet

1. What RAN-LANSOPRAZOLE is and what it is used for

2. What you need to know before you take RAN-LANSOPRAZOLE

3. How to take RAN-LANSOPRAZOLE

4. Possible side effects

5. How to store RAN-LANSOPRAZOLE

6. Contents of the pack and other information

1. What RAN-LANSOPRAZOLE is and what it is used for

RAN-LANSOPRAZOLE capsules are used for the:

- Short term treatment of duodenal ulcers, stomach ulcers and inflammation of the oesophagus caused by acid reflux.

- Is used in conjunction with appropriate antibiotics to destroy a bacteria known as H. Pylori

RAN-LANSOPRAZOLE 15 capsules are used for the:

- Short term management of mild dyspepsia and for the prevention of relapse of oesophagitis caused by acid reflux.

2. What you need to know before you take RAN-LANSOPRAZOLE

Do not take RAN-LANSOPRAZOLE:

- if you are (hypersensitive) to lansoprazole or to any of the other ingredients of RAN-LANSOPRAZOLE (listed in section 6).
- if you are pregnant, or planning to become pregnant, or are breastfeeding.
- if you have severe problems with your liver.
- if you are taking a medicine containing the active substance atazanavir or nelfinavir (used in the treatment of HIV).

Warnings and precautions

Take special care with RAN-LANSOPRAZOLE:

- if you have low magnesium levels in your blood. If you are already taking medicines, [e.g. water tablet (diuretic), digoxin (medicine used to treat heart failure)] that can cause low magnesium level. In this condition, your doctor may monitor magnesium levels in your body before prescribing RAN-LANSOPRAZOLE to you.
- If you are on RAN-LANSOPRAZOLE 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.

RAN-LANSOPRAZOLE is not recommended for children.

Tell your doctor immediately if you notice any of the following symptoms:

- an unintentional loss of weight
- repeated vomiting
- difficulty in swallowing
- vomiting blood
- you look pale and feel weak (anaemia)
- you notice blood in your stools
- severe and/or persistent diarrhoea, as RAN-LANSOPRAZOLE has been associated with a small increase in infectious diarrhoea.

Your doctor may decide that you need some tests to rule out malignant disease because RAN-LANSOPRAZOLE also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.

RAN-LANSOPRAZOLE is not to be taken if your indigestion is caused due to other reasons such as nervousness**.**

RAN-LANSOPRAZOLE can increase the risk of bone fracture. The risk of bone fracture is higher in patients who have received high dose of lansoprazole on a long term basis (longer than 1 year). Your doctor will advise you to use at lowest dose, for shortest period of duration. If you are at risk of bone fracture, contact to your doctor for further advice.

If your doctor has given you **RAN-LANSOPRAZOLE** in addition to other medicines intended for the treatment of *Helicobacter pylori* infection (antibiotics), please also read the package leaflets of these medicines carefully.

If you take **RAN-LANSOPRAZOLE** 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.

Treatment with **RAN-LANSOPRAZOLE** may lead to an increased risk of infections in the stomach and intestines. This may increase your risk of getting severe diarrhoea. This diarrhoea may be caused by an infection (*Clostridium difficile*) in your intestines. Call your doctor right away if you have watery stool, stomach pain, and fever that do not go away.

Proton pump inhibitor medicines, such as **RAN-LANSOPRAZOLE,** may cause tubulointerstitial nephritis which is inflammation that affects the tubules of the kidneys and the tissues that surround them. This condition may progress to kidney failure and is not necessarily reversed when treatment is discontinued, if there is a decrease in the amount that you usually urinate or if you have blood in your urine, contact your doctor immediately.

If you are using RAN-LANSOPRAZOLE over a long period of time (e.g. longer than 3 years) this may lead to a vitamin B12 deficiency.

If you are taking methotrexate.

RAN-LANSOPRAZOLE may make you drowsy and impair your concentration (see "Driving and using machinery").

If you are taking **RAN-LANSOPRAZOLE** for a long period of time, you may be at risk of gastro-intestinal infections such as Salmonella, and Campylobacter

Your doctor may conduct a test known as an endoscopy before prescribing **RAN-LANSOPRAZOLE.**

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Other medicines and RAN-LANSOPRAZOLE

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

Tell your doctor if you are taking:

Warfarin or other anti-coagulants (blood thinning medicines)

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)

Antacids (used to treat heartburn or acid regurgitation)

Sucralfate (used for healing ulcers)

St John's Wort (Hypericum perforatum) (used to treat mild depression)

Methotrexate (medicine used to treat arthritis and some types of cancer)

Ampicillin esters (medicine used to treat bacterial infections)

Iron supplements

Atazanavir/ nelfinavir (medicine commonly used for the treatment of HIV infection). (See also 'Do not take RAN-LANSOPRAZOLE')

Antipyrine, indomethacin, ibuprofen, or other nonsteroidal anti-inflammatory drugs (NSAIDS); (medicines used to treat pain)

Oral contraceptives

Phenytoin (to treat epilepsy),

Propranolol (to treat high blood pressure),

Diazepam (to relax muscles or to treat anxiety)

Clarithromycin (a type of antibiotic)

Dasatinib, erlotinib (to treat cancer).

RAN-LANSOPRAZOLE with food and drink

RAN-LANSOPRAZOLE may be taken with food or on an empty stomach (see section 3).

Pregnancy and breastfeeding

Do not take if you are pregnant or breastfeeding.

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

Driving and using machines

Side effects such as dizziness, vertigo, tiredness and visual disturbances sometimes occur in patients taking **RAN-LANSOPRAZOLE**. If you experience side effects like these you should take caution as your ability to react may be decreased.

Do not take charge of vehicles or machines or perform potentially hazardous tasks where loss of concentration could lead to accidents.

RAN-LANSOPRAZOLE contains sucrose

RAN-LANSOPRAZOLE contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE RAN-LANSOPRAZOLE

Do not share medicines prescribed for you with any other person.

Always take RAN-LANSOPRAZOLE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

The usual dose for adults is one RAN-LANSOPRAZOLE 15 or one RAN-LANSOPRAZOLE 30 once a day depending on the condition you are being treated for.

Gastric ulcer: Take one RAN-LANSOPRAZOLE 30 capsule once daily for up to 8 weeks as directed by your doctor.

Duodenal ulcer: Take 1 RAN-LANSOPRAZOLE 30 capsule once daily for up to 4 weeks as directed by your doctor.

Eradication of H Pylori: Your doctor would advice you to take

RAN-LANSOPRAZOLE capsules along with two appropriate antibiotics.

Oesophagitis due to gastro-oesophageal reflux: Take one (1) RAN- LANSOPRAZOLE 30 capsule once daily for 4 weeks as directed by your doctor. Usually you will feel well within 4 weeks. However depending on the endoscopic results your doctor may decide to repeat treatment with one RAN-LANSOPRAZOLE 30 capsule taken once daily for another 4 weeks.

Maintenance therapy for the prevention of gastro-oesophageal reflux: Your doctor would advise you to continue RAN-LANSOPRAZOLE 15 taken once daily for up to a year to prevent reappearance of your reflux symptoms.

Acid related dyspepsia: Take 15 mg lansoprazole once daily for 2-4 weeks as directed by your doctor.

Swallow the capsule(s) whole with a glass of water. Do not crush or chew the capsule. To achieve the best results the capsules should always be taken before food.

To help you remember to take your medicine, try to get into the habit of taking it at the same time each day.

Take your capsule(s) as directed and for as long as directed; do not stop them, even if you feel better, as otherwise the symptoms may return.

*If you have the impression that the effect of **RAN-LANSOPRAZOLE** capsules are too strong or too weak, talk to your doctor or pharmacist.*

Special dosage instructions for specific populations

Elderly patients

No dose adjustment is necessary. However, 30mg per day is the maximum daily dose.

Kidney and liver impairment

No dose adjustment is necessary in renal failure – this also applies to patients on dialysis.

Paediatric population:

RAN-LANSOPRAZOLE is not recommended for children (See also **'Do not take RAN-LANSOPRAZOLE'**).

If you take more RAN-LANSOPRAZOLE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet or some tablets with you so your doctor will know what you have taken.

If you forget to take RAN-LANSOPRAZOLE:

If you forget to take **RAN-LANSOPRAZOLE** capsules at the right time, take them as soon as you remember. 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 individual doses.

Effects when treatment with RAN-LANSOPRAZOLE is stopped: Do not stop treatment early because your symptoms have improved. Your condition may not have been fully healed and may reoccur if you do not finish your course of treatment.

4 Possible side effects

RAN-LANSOPRAZOLE can have side effects.

Not all side effects reported for RAN-LANSOPRAZOLE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RAN-LANSOPRAZOLE, please consult your healthcare provider for advice.

If any of the following happens, stop taking RAN-LANSOPRAZOLE and tell your doctor immediately or go to the casualty department at your nearest hospital:

Rashes, hives, itching, chest tightness, shortness of breath or swelling of the face, lips, tongue, throat, hands/feet, fainting,

- high temperature,
- severe skin blistering, or soreness or ulcers in your mouth or throat.
- blood in the urine, increased or decreased urine output; mental status changes (drowsiness, confusion, coma), nausea, vomiting.

These are very serious side effects. If you have them, you may have had a serious reaction to RAN-LANSOPRAZOLE. You may need urgent medical attention or hospitalisation.

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

- severe upper stomach pain, often with nausea and vomiting,
- yellowing of the skin or whites of the eyes or fever, rash, and enlarged kidneys sometimes with painful urination and lower back pain,
- chest pain, abnormal or fast or slow heartbeat, heart attack,
- unusual bruising or bleeding,
- frequent infections,
- stroke, paralysis of one half of the body,
- a dangerous decrease of blood pressure which may cause fainting or collapse,
- bleeding from the stomach or intestine,

- shortness of breath, cough, asthma, chills or fever,
- vomiting of blood,
- severe diarrhoea characterised by watery stools, stomach pain, fever (*Clostridium difficile* associated diarrhoea),
- a persistent, raised, red, dry patch on the skin of sun exposed areas such as the neck, arms or chest and back (subacute cutaneous lupus erythematosus),
- low levels of magnesium, can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate.
- low levels of calcium or potassium in the blood

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:

- vomiting, nausea, diarrhoea, constipation, stomach pain or cramps, dry mouth or throat or sore mouth or tongue, and cold sores,
- skin rashes, itching, dry skin, red, sore, or inflamed skin,
- dizziness, headache, tiredness, generalised feeling of being unwell excessive or lack of sleep, hand shaking,
- changes in test results (e.g. raised liver enzymes),

Less frequent side effects:

- impaired or reduced sense of taste; loss of sense of smell,
- mouth ulcers,
- muscle or joint pain,
- pain, back pain, chest pain, neck pain, neck rigidity, pelvic pain, leg cramps,
- heartburn, increased or decreased appetite, increased salivation, thirst,
- hunger, bad breath, abdominal fullness, passing wind, tongue disorder,

- increased sweating, weight gain or weight loss, strained voice (hoarseness),
- diabetes, thyroid problems,
- acne, hives, hair loss, skin eruptions, nail problems, red or purple spots under the skin, purple-coloured spots and patches on the skin,
- increased sensitivity to light,
- bleeding gums, fungal infection of food pipe,
- a change in the way things taste, inflammation of your tongue,
- swollen glands in the neck, armpit or groin,
- vitamin deficiency, gout, dehydration,
- swelling in legs and hands,
- abnormal dreams, agitation, loss of memory, anxiety, lack of interest or excitement, confusion, feeling disconnected, depression, excessive emotional behaviour, increased hostility, unusually overactive, nervousness, restlessness, mental or emotional disorders, abnormal thinking, shaking and seeing, feeling or hearing things that are not there (hallucinations), fits, thinking problems, speech disorder,
- pins and needles,
- unusual muscle stiffness causing poor control of movement, decreased feeling or sensitivity, especially in the skin,
- decreased/increased sexual desire,
- abnormal or blurred vision, double vision, loss of one eye's ability to see details, swollen eyelids, swollen runny eyes, dry eyes, eye pain, disturb visual field,
- deafness, ear problems, ringing in ears, ear infection,
- disturbed menstrual cycle, painful menstrual periods, heavy menstrual periods, breast pain, breast tenderness, breast enlargement in men, unusual secretion of breast milk,
- painful urination, passing more urine than normal, urgency to urinate, impaired urination, urine retention, infection of the urinary tract, kidney stone, pain in kidney, kidney problems,
- erectile dysfunction, penis disorder, testis disorder,
- vaginal discharge, inflammation of the vagina,

- changes in the results of certain laboratory tests (such as sodium, cholesterol, triglyceride, or sugar levels) or changes in blood cell counts.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction 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 RAN-LANSOPRAZOLE.

5.How to store RAN-LANSOPRAZOLE

- Store all medicines out of reach of children.
- Store at or below 25 °C
- Store in the original package/ container.
- Keep the container in the outer carton.
- Keep the container tightly closed.
- Do not remove the blister strips from the cartons until required for use.
- Protect from light and moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label/ carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What RAN-LANSOPRAZOLE contains

The active substance is lansoprazole.

RAN-LANSOPRAZOLE capsules also contains the following inactive ingredients:

The capsule contains colloidal anhydrous silica, hydroxypropyl methyl cellulose, macrogol 300, methacrylic acid- ethylacrylate copolymer (1:1) dispersion 30 %, purified talc, purified water, sucrose and titanium dioxide.

The 15 mg capsule shell consists of yellow cap/yellow body consisting of Gelatin, quinoline yellow, yellow iron oxide; titanium dioxide.

Printing Ink: Opacode Black S-I-8152 HV consisting of iron oxide black, shellac glaze, soya lecithin.

The 30 mg capsule shell consists of purple cap/lavender body consisting of Azorubine; Indigo carmine; gelatin, titanium dioxide.

Printing Ink: ammonium hydroxide 2 %; ethanol, isopropyl alcohol, iron oxide black, N-butyl alcohol; propylene glycol; purified water, shellac glaze.

What RAN-LANSOPRAZOLE looks like and contents of the pack

RAN-LANSOPRAZOLE 15: Yellow cap/yellow body, self locked hard gelatin capsule of size '3' imprinted with 'L 15' on both cap and body containing white to off-white pellets.

RAN-LANSOPRAZOLE 30: Purple cap/lavender body, self locked hard gelatin capsule of size '1' imprinted with 'L 30' on both cap and body containing white to off-white pellets.

7 capsules are packed in cold form blister strips or aluminium strips.

Cold form blister strips comprise of a cold form laminate with a backing of aluminium foil sealed with a heat seal lacquer.

Aluminium strips comprise of aluminium foil laminated with low-density polyethylene.

Cartons contain 7, 14 or 28 capsules.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

A Sun Pharma Company

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South Africa

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Registration number

RAN-LANOPRAZOLE 15: A39/11.4.3/0251

RAN-LANSOPRAZOLE 30: A39/11.4.3/0252

Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd
Product name: Ran-Lansoprazole 15 & 30
Dosage form: Capsules
Strength: 15/ 30 mg Lansoprazole/capsule

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

RAN-LANSOPRAZOLE 15 kapsules/

RAN-LANSOPRAZOLE 30 kapsules

Lansoprasool 15 mg/ 30 mg

Bevat suiker (sukrose)

Elke 15 mg kapsule bevat 80 mg sukrose.

Elke 30 mg **k**apsule bevat 160 mg sukrose.

Lees die hele inligtingstuk noukeurig deur voordat jy begin om RAN- LANSOPRAZOLE te neem

- Hou hierdie inligtingstuk. Jy sal dit moontlik weer moet lees.
- Vra asseblief jou dokter of apteker indien jy verdere vrae het.
- **RAN-LANSOPRAZOLE** is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met ander persone deel nie. Dit kan skadelik vir hulle wees, selfs as hulle simptome dieselfde as joune is.

Wat is in hierdie inligtingstuk

1. Wat **RAN-LANSOPRAZOLE** is en waarvoor dit gebruik word

2. Wat jy moet weet voordat jy **RAN-LANSOPRAZOLE** neem

3. Hoe om **RAN-LANSOPRAZOLE** te neem

4. Moontlike newe-effekte

5. Hoe om **RAN-LANSOPRAZOLE** te bewaar

6. Inhoud van die verpakking en ander inligting

1. Wat RAN-LANSOPRAZOLE is en waarvoor dit gebruik word

RAN-LANSOPRAZOLE kapsules word gebruik vir die:

- korttermyn behandeling van duodenale ulkusse (sere), maagulkusse en inflammasie van die slukderm wat deur die terugvloei van maagsuur veroorsaak word.

- gelyktydige gebruik saam met gepaste antibiotika om ‘n bakterie bekend as *H. pylori* te vernietig.

RAN-LANSOPRAZOLE 15 kapsules word gebruik vir die:

- korttermyn behandeling van ligte buikongemak en vir die voorkoming van terugval van inflammasie van die slukderm veroorsaak deur terugvloei van maagsuur.

2. Wat jy moet weet voordat jy RAN-LANSOPRAZOLE neem

Moenie RAN-LANSOPRAZOLE neem nie:

- as jy allergies (hipersensitief) is vir lansoprasool of vir enige van die ander bestanddele van **RAN-LANSOPRAZOLE** (gelys in afdeling 6).
- as jy swanger is, of beplan om swanger te raak, of as jy borsvoed.
- as jy ernstige probleme met jou lewer het.
- as jy ‘n middel neem wat die aktiewe bestanddeel atasanavir of nelfinavir (gebruik vir die behandeling van MIV) bevat.

Waarskuwings en voorsorgmaatreëls

Tref spesiale voorsorg met RAN-LANSOPRAZOLE:

- as jy lae magnesiumvlakke in jou bloed het. As jy alreeds medisyne neem, [bv.’n watertablet (diuretikum), digoksien (medisyne wat gebruik word om hartversaking te behandel)] wat lae magnesiumvlakke kan veroorsaak. In hierdie geval sal jou dokter magnesiumvlakke in jou liggaam monitor voordat **RAN-LANSOPRAZOLE** aan jou voorgeskryf word.
- As jy langer as drie maande op RAN-LANSOPRAZOLE is, is dit moontlik dat die vlakke van magnesium in jou bloed kan daal. Lae vlakke van magnesium kan moegheid, onwillekeurige spiersametrekkings, disoriëntasie, stuiptrekkings, duiseligheid en verhoogde hartklop veroorsaak. As jy enige van hierdie simptome ervaar, vertel asseblief jou dokter dadelik. Lae vlakke van magnesium kan ook lei tot 'n afname in kalium- of kalsiumvlakke in die bloed. Jou dokter kan besluit om gereelde bloedtoetse te doen om jou magnesium bloedvlakke te monitor.

RAN-LANSOPRAZOLE word nie vir kinders aanbeveel nie.

Lig jou dokter onmiddellik in indien jy enige van die volgende simptome opmerk:

- ‘n onbeplande gewigsverlies
- hehaaldelike braking
- probleme om te sluk
- gooi bloed op
- jy bleek lyk en swak voel (anemie)
- jy bloed in jou stoelgang opmerk
- erge en/of aanhoudende diarree, aangesien **RAN-LANSOPRAZOLE** met ‘n klein toename in aansteeklike diarree geassosieer word.

Jou dokter kan besluit dat jy sommige toetse nodig het om kwaadaardige siekte uit te sluit omdat **RAN-LANSOPRAZOLE** ook die simptome van kanker verlig en kon ‘n vertraging veroorsaak om dit te diagnoseer. Indien jou simptome voortduur ten spyte van jou behandeling, sal verdere ondersoeke oorweeg word.

RAN-LANSOPRAZOLE moet nie geneem word as jou spysverteringsprobleme veroorsaak word as gevolg van ander redes soos senuweeagtigheid nie.

RAN-LANSOPRAZOLE kan die risiko van beenbreuke verhoog. Die risiko van beenbreuk is groter by pasiënte wat ‘n hoë dosis van lansoprasool oor ‘n lang tydperk ontvang het (langer as 1 jaar). Jou dokter sal jou aanraai om die laagste dosis vir die korste tydperk te gebruik. Indien jy ‘n risiko het vir ‘n beenbreuk, moet jy jou dokter raadpleeg vir verdere advies.

As jou dokter **RAN-LANSOPRAZOLE** aan jou voorgeskryf het saam met ander medisyne wat bedoel is vir die behandeling van *Helicobacter pylori*-infeksie (antibiotika), moet jy asseblief ook die inligtingstukke van hierdie medisyne noukeurig lees.

Indien jy **RAN-LANSOPRAZOLE** op ‘n langtermynbasis (langer as 1 jaar) gebruik, sal jou dokter waarsynlik gereeld toesig oor jou hou. Jy moet enige nuwe of uitsonderlike simptome en omstandighede aanmeld wanneer jy jou dokter sien.

Behandeling met **RAN-LANSOPRAZOLE** kan tot ‘n verhoogde risiko van infeksies in die maag en ingewande lei. Dit kan jou risiko verhoog om ernstige diarree te ontwikkel. Hierdie diarree kan deur ‘n infeksie (*Clostridium difficile*) in jou ingewande veroorsaak word. Kontak jou dokter dadelik as jy ‘n waterige stoelgang, maagpyn en koors het wat nie wil verdwyn nie.

Protonpomp-inhibeerder medisyne, soos **RAN-LANSOPRAZOLE,** kan tubulointerstisiële nefritis veroorsaak wat onsteking is wat die buise van die niere en die weefsel wat dit omring affekteer. Hierdie toestand kan vorder tot

nierversaking en is nie noodwendig omkeerbaar wanneer behandeling gestaak word nie. Indien daar ‘n afname is in die hoeveelheid wat jy gewoonlik urineer of as jy bloed in jou urine het, moet jy jou dokter onmiddellik kontak.

Indien jy **RAN-LANSOPRAZOLE** oor ‘n lang tydperk gebruik (bv. langer as 3 jaar) kan dit lei tot ‘n vitamien B_{12} tekort.

As jy metotreksaat gebruik.

RAN-LANSOPRAZOLE kan jou lomerig maak en jou konsentrasie belemmer (sien “Bestuur van voertuie en gebruik van masjinerie”).

As jy **RAN-LANSOPRAZOLE** vir ‘n lang tydperk gebruik, kan jy ‘n risiko hê van gastroïntestinale infeksies soos Salmonella en Campylobacter.

Jou dokter kan ‘n prosedure uitvoer wat bekend is as endoskopie voordat **RAN-LANSOPRAZOLE** aan jou voorgeskryf word**.**

Raadpleeg jou dokter, selfs as hierdie bewerings op enige tydstip in die verlede op jou van toepassing was.

Ander medisyne en RAN-LANSOPRAZOLE

Lig jou gesondheidsorgverskaffer altyd in as jy ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Lig jou dokter in as jy die volgende gebruik:

Warfarien of ander antistolmiddels (bloedverdunningsmiddels)

Ketokonasool, itrakonasool, rifampisien (gebruik om infeksies te behandel)

Digoksien (gebruik om hartprobleme te behandel)

Teofillien (gebruik om asma te behandel)

Takrolimus (gebruik om verwerping tydens oorplanting te voorkom)

Fluvoksamien (gebruik om depressie en ander psigiatriese siektes te behandel)

Teensuurmiddels (gebruik om sooibrand of suurterugstroming te behandel)

Sukralfaat (gebruik om ulkusse gesond te maak)

Johanneskruid (‘St John’s Wort’)(*Hypericum perforatum*) (gebruik om ligte depressie te behandel)

Metotreksaat (medisyne wat gebruik word om artritis en sommige tipes kanker te behandel)

Ampisillienesters (medisyne wat gebruik word om bakteriële infeksies te behandel)

Ysteraanvullers

Atasanavir/ nelfinavir (medisyne wat oor die algemeen gebruik word by die behandeling van MIV-infeksie).

(Sien ook 'Moenie **RAN-LANSOPRAZOLE** neem nie')

Antipirien, indometasien, ibuprofeen, of ander nie-steroïdale anti-inflammatoriese geneesmiddels (NSAIDs);

(medisynes wat gebruik word om pyn te behandel)

Orale voorbehoedmiddels

Fenitoïen (om epilepsie te behandel),

Propranolol (om hoë bloeddruk te behandel),

Diasepam (om spiere te verslap of angstigheid te behandel)

Klaritromisien (‘n tipe antibiotikum)

Dasatinib, erlotinib (om kanker te behandel).

RAN-LANSOPRAZOLE saam met voedsel en drinkgoed

RAN-LANSOPRAZOLE kan saam met voedsel of op ‘n leë maag geneem word (sien afdeling 3).

Swangerskap en borsvoeding

Moenie gebruik as jy swanger is of borsvoed nie.

As jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om ‘n baba te hê, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg vir advies voordat jy hierdie medisyne gebruik.

Bestuur van voertuie en gebruik van masjinerie

Newe-effekte soos duiseligheid, vertigo, moegheid en visuele versteurings kom somtyds voor by pasiënte wat **RAN-LANSOPRAZOLE** neem. Indien jy newe-effekte soos hierdie ervaar, moet jy versigtig wees aangesien jou vermoë om te reageer verminder kan wees.

Moenie voertuie bestuur of masjinerie hanteer of potensiële gevaarlike take uitvoer waar verlies aan konsentrasie tot ongelukke kan lei nie.

RAN-LANSOPRAZOLE bevat sukrose

RAN-LANSOPRAZOLE bevat sukrose. As jy deur jou dokter ingelig is dat jy ‘n onverdraagsaamheid teenoor sekere suikers het, moet jy jou dokter kontak voordat jy hierdie medisyne gebruik.

3. HOE OM RAN-LANSOPRAZOLE TE NEEM

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem **RAN-LANSOPRAZOLE** altyd presies soos wat jou dokter dit voorgeskryf het. Jy moet met jou dokter of apteker bevestig as jy nie seker is nie.

Die gewone dosis vir volwassenes is een **RAN-LANSOPRAZOLE** 15 of een **RAN-LANSOPRAZOLE** 30 een keer per dag afhangende van die toestand waarvoor jy behandel word.

Maagulkus: Neem een **RAN-LANSOPRAZOLE** 30 kapsule een keer per dag vir tot 8 weke soos deur jou dokter voorgeskryf.

Duodenale ulkus: Neem een **RAN-LANSOPRAZOLE** 30 kapsule een keer per dag vir tot 4 weke soos deur jou dokter voorgeskryf.

Uitwissing van H pylori: Jou dokter sal jou aanraai om **RAN-LANSOPRAZOLE** kapsules saam met twee geskikte antibiotika te neem.

Esofagitis as gevolg van gastro-esofageale refluks: Neem een (1) **RAN- LANSOPRAZOLE 30** kapsule een keer per dag vir 4 weke soos deur jou dokter voorgeskryf. Jy sal gewoonlik binne 4 weke beter voel. Nietemin, afhangende van die endoskopiese uitslag, kan jou dokter besluit om die behandeling te herhaal met nog een **RAN-LANSOPRAZOLE 30** kapsule een keer per dag vir 4 weke te neem.

Instandhoudingsterapie vir die voorkoming van gastro-esofageale refluks: Jou dokter sal jou aanraai om voort te gaan om **RAN-LANSOPRAZOLE** 15 een keer per dag te neem vir tot vir ‘n jaar om herverskyning van jou reflukssimptome te voorkom.

Suurverwante dispepsie: Neem 15 mg **RAN-LANSOPRAZOLE** een keer per dag vir 2-4 weke soos voorgeskryf deur jou dokter.

Sluk die kapsule(s) heel in met ‘n glas water. Moenie die kapsuels fynmaak of kou nie. Om die beste resultate te kry, moet die kapsules altyd voor voedsel geneem word.

Om jou te help onthou om jou medisyne te neem, probeer om in die gewoonte te kom om dit op dieselfde tyd elke dag te neem.

Neem jou kapsule(s) soos voorgeskryf en vir so lank as wat dit voorgeskryf is; moenie daarmee ophou nie, selfs as jy beter voel, aangesien die simptome andersins kan terugkeer.

*As jy onder die indruk is dat die effek van **RAN-LANSOPRAZOLE** kapsules te sterk of te swak is, praat met jou dokter of apteker.*

Spesiale doseringsinstruksies vir spesifieke populasies

Bejaarde pasiënte

Geen dosisaanpassing is nodig nie. Die maksimum daaglikse dosis is egter 30 mg per dag.

Nier- en lewerinkorting

Geen dosisaanpassing is nodig in nierversaking nie – dit is ook van toepassing by pasiënte op dialise.

Pediatriese populasie

RAN-LANSOPRAZOLE word nie vir kinders aanbeveel nie (Sien ook **'Moenie RAN-LANSOPRAZOLE neem nie'**).

As jy meer RAN-LANSOPRAZOLE geneem het as wat jy behoort te neem

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. Neem hierdie inligtingstuk of sommige kapsules saam met jou sodat jou dokter kan weet wat jy geneem het.

As jy vergeet het om RAN-LANSOPRAZOLE te neem:

As jy vergeet het om jou **RAN-LANSOPRAZOLE** kapsules op die regte tyd te neem, neem dit so gou as wat jy onthou. As dit egter amper tyd is vir jou volgende dosis, slaan die dosis oor wat jy vergeet het en gaan terug na jou normale dosisskedule. Moenie ‘n dubbele dosis neem op te vergoed vir die individuele dosisse wat jy vergeet het nie.

Effekte wanneer behandeling met RAN-LANSOPRAZOLE gestaak word: Moenie vroeg ophou met die behandeling nie omdat jou simptome verbeter het nie. Jou toestand mag nog nie ten volle genees het nie en mag weer voorkom indien jy nie die kursus van behandeling voltooi het nie.

4 Moontlike newe-effekte

RAN-LANSOPRAZOLE kan newe-effekte hê.

Nie alle newe-effekte wat vir **RAN-LANSOPRAZOLE** aangemeld word, is in hierdie inligtingstuk ingesluit nie. Indien jou algemene gesondheid versleg of as jy enige nadelige effekte ervaar terwyl jy **RAN-LANSOPRAZOLE** neem, moet jy asseblief jou gesondheidsorgverskaffer raadpleeg vir advies.

Indien enige van die volgende gebeur, staak die gebruik van **RAN-LANSOPRAZOLE** en lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal:

· Uitslag, galbulte, gejeuk, benoude bors, kortasemigheid of swelling van die gesig, lippe, tong, keel, hande/voete, floute,

· hoë koors,

· ernstige blasievorming op die vel, of seerheid of ulkusse in jou mond of keel.

· bloed in die urine, verhoogde of verlaagde uitset van urine; veranderinge in geestestoestand (lomerigheid, verwarring, koma),

- naarheid, braking.

Hierdie is almal baie ernstige newe-effekte. As jy dit het, kon jy ‘n ernstige reaksie teen **RAN-LANSOPRAZOLE** gehad het. Jy mag dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

· erge maagpyn in die boonste deel van die maag, dikwels met naarheid en braking,

· vergeling van die vel of wit van die oë of koors, uitslag, vergrote niere; somtyds met pynlike urinering en lae rugpyn,

· borskaspyn, abnormale of vinnige of stadige hartklop, hartaanval,

· ongewone kneusing of bloeding,

· herhaalde infeksies,

· beroerte, verlamming van een helfte van die liggaam,

· ‘n gevaarlike afname in bloeddruk wat floute of ineenstorting kan veroorsaak,

· bloeding vanuit die maag of ingewande,

· kortasemigheid, hoes, asma, kouekoors of koors,

· braking van bloed,

· ernstige diarree gekenmerk deur waterige stoelgange, maagpyn, koors (*Clostridium difficile*-geassosieerde diarree).

· ‘n aanhoudende, opgehewe, rooi, droë gedeelte op die vel van areas wat aan die son blootgestel is soos die nek, arms of borskas en rug (subakute kutaneuse lupus erythematosus).

· lae vlakke van magnesium kan waargeneem word as uitputting, onwillekeurige spiersametrekkings, disoriëntasie, konvulsies, duiseligheid, verhoogde hartritme.

· lae vlakke van kalsium of kalium in die bloed.

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese aandag nodig hê.

Lig jou dokter in as jy enige van die volgende opmerk:

Algemene newe-effekte:

· braking, naarheid, diarree, hardlywigheid, maagpyn of krampe, droë mond of keel of seer mond of tong en koorsblare,

· veluitslag, jeukerigheid, droë vel, rooi, seer, of ontsteekte vel,

· duiseligheid, hoofpyn, moegheid, algemene onwel gevoel, oormatige of tekort aan slaap, rukking van die hande,

- veranderinge in toetsuitslae (bv. verhoogde lewerensieme).

Minder algemene newe-effekte:

· belemmerde of verminderde smaaksensasie; verlies van reuksensasie,

· mondsere,

· spier- of gewrigspyne,

· pyn, rugpyn, borskaspyn, nekpyn, nekstyfheid, pelviese pyn, krampe in die bene,

· sooibrand, verhoogde of verlaagde aptyt, verhoogde speeksel, dors,

· honger, slegte asem, abdominale volheid, laat winde, tongversteuring,

· verhoogde sweet, gewigstoename of gewigsverlies, geforseerde stem (heesheid),

· diabetes, tiroïedprobleme,

· aknee, galbulte, haarverlies, veluitbarstings, naelprobleme, rooi of pers kolle onder die vel, pers-gekleurde kolle en gedeeltes op die vel,

· verhoogde sensitiwiteit vir lig,

· bloeiende tandvleise, fungusinfeksie van slukderm,

· ‘n verandering in die manier wat dinge proe, ontsteking van jou tong,

· geswelde kliere in die nek, armholte of lies,

· vitamientekort, jig, dehidrasie,

· swelling van bene en hande,

· abnormale drome, opwinding, geheueverlies, angstigheid, verlies aan belangstelling of opgewondenheid, verwarring, voel afgesluit, depressie, uitermatige emosionele gedrag, verhoogde vyandigheid, ongewone ooraktiwiteit, senuweeagtigheid, rusteloosheid, geestes- of emosionele versteurings, abnormale denke,

bewerigheid en sien, voel of hoor dinge wat nie bestaan nie (hallusinasies), aanvalle, probleme met gedagtes, spraakversteuring,

· naalde en spelde-gevoel,

· ongewone spierstyfheid wat swak beheer van beweging veroorsaak, verminderde gevoel of sensitiwiteit, veral in die vel,

· verlaagde/verhoogde seksuele begeerte,

· abnormale of dowwe visie, dubbelvisie, verlies van een oog se vermoë om detail waar te neem, geswelde ooglede, geswelde waterige oë, droë oë, oogpyn, versteurde gesigsveld,

· doofheid, oorprobleme, gesuis in ore, oorinfeksie,

· versteurde menstruele siklus, pynlike maandstondes, swaar maandstondes, borspyn, teerheid van borste, borsvergroting by mans, ongewone sekresie van borsmelk,

· pynlike urinering, passeer meer urine as gewoonlik, dringendheid om te urineer, belemmerde urinering, urienretensie, infeksie van die urienweg, niersteen, pyn in die nier, nierprobleme,

· erektiele wanfunksie, penisversteuring, testisversteuring,

· vaginale afskeiding, ontsteking van die vagina,

· veranderinge in die uitslag van sekere laboratoriumtoetse (soos natrium-, cholesterol-, trigliseried-, of suikervlakke) of veranderinge in bloedseltellings.

Indien jy enige newe-effekte waarneem wat nie in hierdie inligtingstuk genoem word nie, moet jy asseblief jou dokter of apteker inlig.

Aanmelding van newe-effekte

Praat met jou dokter, apteker of verpleegkundige as jy newe-effekte ervaar. Jy kan ook newe-effekte aanmeld by SAHPRA *via* die "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn beskikbaar is 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 **RAN-LANSOPRAZOLE** te verskaf.

5.Hoe om RAN-LANSOPRAZOLE te bewaar

- Bewaar alle medisyne buite die bereik van kinders.
- Bewaar by of onder 25 °C.
- Bewaar in die oorspronklike verpakking/ houer.
- Hou die houer in die buitenste karton.

- Hou die houer dig toe.
- Moenie die stulpstrole uit die kartonne verwyder tot benodig vir gebruik nie.
- Beskerm teen lig en vog.
- Moenie in die badkamer bewaar nie.
- Moenie na die vervaldatum soos op die etiket/karton gebruik nie.
- Bring alle ongebruikte medisyne terug na jou apteker toe.
- Moenie van ongebruikte medisyne in dreinering- of rioleringstelsels (bv. toilette) ontslae raak nie.

6. Inhoud van die verpakking en ander inligting

Wat RAN-LANSOPRAZOLE bevat

Die aktiewe bestanddeel is lansoprasool.

RAN-LANSOPRAZOLE kapsules bevat ook die volgende bestanddele:

Die kapsules bevat kolloïdale anhidriese silika, hidroksipropiel-metielsellulose, makrogol 300, metakrilliese suur-etielakrilaat ko-polimeer (1:1)-mengsel 30 %, gesuiwerde talk, gesuiwerde water, sukrose en titaniumdioksied.

Die 15 mg kapsule-dop bestaan uit ‘n geel doppie/geel romp wat bestaan uit gelatien, geel-kinolien, geel-ysteroksied; titaniumdioksied.

Drukkersink: swart Opacode S-I-8152 HV wat bestaan uit swart-ysteroksied, skellakglasuur, sojalesitien.

Die 30 mg kapsule-dop bestaan uit ‘n pers doppie/laventel romp wat bestaan uit asorubien; indigokarmyn; gelatien, titaniumdioksied.

Drukkersink: ammoniumhidroksied 2 %; etanol, isopropielalkohol, swart ysteroksied, N-butiel-alkohol; propileenglikool; gesuiwerde water, skellakglasuur.

Hoe RAN-LANSOPRAZOLE lyk en inhoud van die verpakking

RAN-LANSOPRAZOLE 15: Geel doppie/geel romp, selfsluitende harde gelatienkapsule van grootte '3' gedruk met 'L 15' op beide die doppie en romp; bevattende wit tot naaswit korreltjies.

RAN-LANSOPRAZOLE 30: Pers doppie/laventel romp, selfsluitende harde gelatienkapsule van grootte '1' gedruk met 'L 30' op beide die doppie en romp; bevattende wit tot naaswit korreltjies.

7 kapsules word verpak in kouevorm-stulpstroke of aluminiumstroke.

Kouevorm-stulpstroke bestaan uit ‘n kouevormlaminaat met ‘n rugkant van aluminiumfoelie verseël met hitte-seëllak.

Aluminiumstroke bestaan uit aluminiumfoelie gelamineer met lae-digtheid poliëtileen.

Kartonne bevat 7, 14 of 28 kapsules.

Houer van Registrasiesertifikaat

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'n Sun Pharma maatskappy

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Suid-Afrika

Hiedie inligtingstuk was laas hersien op

03 Mei 2024

Registrasienommers

RAN-LANOPRAZOLE 15: A39/11.4.3/0251

RAN-LANSOPRAZOLE 30: A39/11.4.3/0252

Ran-Lansoprazole 15

Namibië: NS2 Reg.No.: 07/11.4.3/0034

Botswana: S2 Reg No.: BOT0701091

Ran-Lansoprazole 30

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Botswana: S2 Reg No.:BOT0701092