

Proposed Patient Information Leaflet – Clean Copy

SCHEDULING STATUS S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

RAN-LANSOPRAZOLE 15 (capsules)

RAN-LANSOPRAZOLE 30 (capsules)

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.

1. WHAT RAN-LANSOPRAZOLE CONTAINS

RAN-LANSOPRAZOLE capsules contain lansoprazole as the active ingredient.

Each **RAN-LANSOPRAZOLE 15** capsule contains: Lansoprazole 15 mg

Sugar (sucrose) 80 mg

Each **RAN-LANSOPRAZOLE 30** capsule contains: Lansoprazole 30 mg

Sugar (sucrose) 160 mg

RAN-LANSOPRAZOLE capsules also contain the following inactive ingredients:

Colloidal anhydrous silica, empty hard gelatin capsule shell, hydroxypropyl methyl cellulose, macrogol 300, methacrylic acid- ethylacrylate copolymer (1:1) dispersion 30 %, purified talc, purified water and titanium dioxide.

Contains sugar: sucrose.

2. WHAT THIS MEDICINE 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.

3. BEFORE TAKING RAN-LANSOPRAZOLE

Do not take RAN-LANSOPRAZOLE:

- if you are allergic to lansoprazole or to any of the other ingredients of **RAN-LANSOPRAZOLE**.
- 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).

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.

RAN-LANSOPRAZOLE is not recommended for children.

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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 **RAN-LANSOPRAZOLE** 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 rarely 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.

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

Taking RAN-LANSOPRAZOLE with food and drink

RAN-LANSOPRAZOLE may be taken with food or on an empty stomach.

Pregnancy and Breastfeeding:

Do not take **RAN-LANSOPRAZOLE** if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **RAN-LANSOPRAZOLE**.

Driving and using machinery:

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.

Taking other medicines with RAN-LANSOPRAZOLE

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

(This includes 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 (medicine commonly used for the treatment of HIV infection). (See also **'Do not take RAN-LANSOPRAZOLE:'**)

4. 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.

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 advise 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.*

If you take more RAN-LANSOPRAZOLE than you should:

In the event of over-dosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. Take this leaflet or some medicine with you so your doctor will know what you have taken.

If you missed a dose of 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.

5. POSSIBLE SIDE-EFFECTS

RAN-LANSOPRAZOLE capsules 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 doctor, pharmacist or other healthcare professional 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 (If you have them, you may have had a serious allergic reaction to **RAN- LANSOPRAZOLE**),
- high temperature,
- severe skin blistering, or soreness or ulcers in your mouth or throat. These are very serious side effects. 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).

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

Tell your doctor if you notice any of the following:

- vomiting, nausea, diarrhoea, constipation, stomach pain or cramps, dry or sore mouth or tongue, mouth ulcers and cold sores,
- dizziness, headache, tiredness, generalised feeling of being unwell, excessive or lack of sleep, hand shaking,
- 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,
- impaired or reduced sense of taste; loss of sense of smell,
- 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, itching, hives, hair loss, skin rash, dry skin, skin eruptions, nail problems, red or purple spots under the skin, purple-coloured spots and patches on the skin, red, sore, or inflamed 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,
- disturb 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.

6. STORING AND DISPOSING OF RAN-LANSOPRAZOLE

Store below 25 °C, in the original container protected from light and moisture.

Do not remove blisters from the carton until required for use.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems.

7. PRESENTATION OF RAN-LANSOPRAZOLE

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.

8. IDENTIFICATION OF RAN-LANSOPRAZOLE

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.

9. REGISTRATION NUMBER

RAN-LANSOPRAZOLE 15: A39/11.4.3/0251

RAN-LANSOPRAZOLE 30: A39/11.4.3/0252

10. NAME AND ADDRESS OF REGISTRATION HOLDER

RANBAXY PHARMACEUTICALS (PTY) LTD

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South Africa

11. DATE OF PUBLICATION

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