

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

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

RAN-LANSOPRAZOLE 15 capsules/

RAN-LANSOPRAZOLE 30 capsules

Lansoprazole 15 mg/ 30 mg

Contains sugar (sucrose)

Each 5 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.

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- 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.

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.

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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.

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Other medicines and RAN-LANSOPRAZOLE

Always tell your health care 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).

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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 health care 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 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

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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.

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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 health care 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,

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- 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.

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,

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- 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.

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- 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.

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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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