

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S4****REPIGUT 20 mg gastric-resistant tablets****REPIGUT 40 mg gastric-resistant tablets****Esomeprazole****Contains sugar: sucrose and lactose monohydrate:****sucrose 11,875 to 17,385 mg and lactose monohydrate 72,06 to 77,33 mg per tablet.****Read all of this leaflet carefully before you start taking REPIGUT**

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

1. What REPIGUT is and what it is used for

Esomeprazole belongs to a group of medicines called “proton pump inhibitors”. They work by reducing the amount of acid that your stomach produces.

Esomeprazole, contained in REPIGUT is used for treating the following conditions:

- “Gastroesophageal reflux disease” (GORD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Ulcers in the stomach or upper part of the gut (intestine) that are infected with bacteria called *Helicobacter pylori*. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Esomeprazole can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

2. What you need to know before you take REPIGUT

Do not take REPIGUT:

- If you are hypersensitive (allergic) to esomeprazole or any of the other ingredients of REPIGUT (listed in section 6).
- If you are allergic to other “proton pump inhibitors”.
- If you are taking medication for HIV treatment (atazanavir or nelfinavir).

Warnings and precautions

Tell your doctor or health care provider before taking REPIGUT:

- If you have been experiencing indigestion

- If you have been on continuous medication for longer than a year
- If you have been taking a medication that contains clopidogrel (used in the treatment of blood clots)
- If you are due to have a specific blood test (Chromogranin A).
- If you have had previous intestinal conditions
- If you develop severe diarrhoea that has watery stools, abdominal pain, and fever
- If you are taking REPIGUT when necessary and your symptoms change
- If you have vitamin B₁₂ deficiency
- If you develop tiredness dizziness, tremor, and muscle problems (hypomagnesaemia)
- If you have been diagnosed with osteoporosis (brittle bones) or are at risk of breaking your bones
- If you develop 'butterfly rash' with sensitivity to sun light (subacute cutaneous lupus erythematosus)
- If you develop kidney problems such as cloudy urine, pain in the kidney area, blood or pus in the urine, frequent urination

If any of these applies to you, tell your doctor or nurse before you are given REPIGUT

Children

REPIGUT should not be used in children younger than 12 years.

Other medicines and REPIGUT

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

It is particularly important that you mention the following:

- Itraconazole, ketoconazole voriconazole used in the treatment of fungal infections
- Diazepam used in the treatment of anxiety
- Medicines used to prevent fitting (phenytoin),

- Medicines used to prevent blood clotting (warfarin or clopidogrel),
- Medicine used to help the symptoms of intermittent claudication (cilostazol),
- Medicines used to speed up stomach emptying (cisapride),
- Digoxin used in the treatment of heart problems
- Rifampicin used for the treatment of Tuberculosis
- St. John's Wort - used to treat depression, or certain type of antimalignancy medicines (such as erlotinib or another antimalignancy medicine from the same class.
- REPIGUT should not be taken at the same time as some medicines for HIV, such as atazanavir and nelfinavir, as REPIGUT may reduce the blood levels of your antiretroviral medicine.
- Tipranavir used to treat HIV
- Clarithromycin, an antibiotic
- Tacrolimus used to prevent organ transplant rejection
- If you are taking a high dose of methotrexate (a chemotherapy medicine in which high dose is used to treat cancer), REPIGUT may need to be temporarily withdrawn.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist, or other healthcare professional for advice before taking this medicine. You should not take REPIGUT if you are pregnant or breastfeeding your baby.

Driving and using machines

REPIGUT may cause dizziness and blurred vision, thereby affecting the ability to drive or use machinery.

REPIGUT contains sugar in the form of sucrose and lactose monohydrate

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 REPIGUT

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

Always take REPIGUT exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The tablets should not be chewed or crushed. They should be swallowed whole, with liquid.

Adults & Adolescents (12 – 18 years)

- *Gastro-Oesophageal Reflux Disease (GORD)*
 - To treat an inflamed food pipe caused by gastroesophageal reflux disease (GORD):
40 mg once daily for 4 weeks
 - Long-term management of patients with healed inflammation: 20 mg once daily
- *Patients requiring continued NSAID (Non-Steroidal Anti-Inflammatory Drugs) therapy*
 - To prevent stomach ulcers if you are taking NSAIDs: 20 mg or 40 mg once daily
- *Eradication of Helicobacter pylori and healing of Helicobacter pylori associated ulcers:*
 - 20 mg REPIGUT with 1 g amoxicillin and 500 mg clarithromycin, all twice daily for 7 days
- *To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome)*
 - The recommended initial dosage is 40 mg twice daily. The dosage should then be individually adjusted, and treatment continued as long as clinically indicated

If you take more REPIGUT than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take REPIGUT

Do not take a double dose to make up for forgotten individual doses. However, if it is almost time for your next dose, do not take the missed dose, and just take the next dose on time.

4. Possible side effects

REPIGUT can have side effects.

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

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

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Rash or itching in the form of Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose, and genitals. This could be 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'.
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

These are all very serious side effects. If you have them, you may have had a serious reaction These are all very serious side effects. If you have them, you may have had a serious reaction to REPIGUT. 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:

- Tightening of chest accompanied with severe coughing (bronchospasm)
- Loss or decreased vision
- Abdominal swelling (may be an indication of liver failure)
- Excessive sweating
- Blood in the urine (Nephritis)
- Significant reduction in the amount of urine with shortness of breath (This could be a sign of kidney failure)

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

- Stomach pain
- Diarrhoea
- Nausea/Vomiting
- Constipation
- Headache

Less frequent side effects

- Muscle weakness/pain
- Fever
- Development of breast tissue in males
- Joint pain
- Hair loss
- Dry mouth
- Inflammation of the mouth and lips

- Dizziness
- Blurred vision
- Tingling sensation
- Loss of balance
- Taste disturbance
- Sleepiness
- Inability to sleep.
- Confusion
- Depression
- Agitation
- Hallucination
- Low white blood cell count

Side effects of which frequency is unknown:

- Decreased levels of calcium
- Decreased levels of magnesium
- “Butterfly rash” that lasts hours – days

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. You can also report side effects to SAHPRA via the Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions 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 REPIGUT.

5. How to store REPIGUT

Store all medicines out of reach of children.

- Store in a dry place at or below 25 °C.
- Keep the blisters in the carton until required for use.
- 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 (e.g. toilets).

6. Contents of the pack and other information

What REPIGUT contains

The active substance is esomeprazole magnesium dihydrate.

The other ingredients are crospovidone, glyceryl monostearate 40-55, HPMC 2910/hypromellose, hydroxy propyl cellulose, iron oxide red, iron oxide yellow, macrogol/PEG, magnesium stearate, meglumine, methacrylic acid copolymer, polysorbate 80, poloxamer 188, silica colloidal anhydrous, silicified microcrystalline cellulose, sodium hydroxide, sodium lauryl sulphate, Starlac (lactose monohydrate and maize starch), sugar spheres (sucrose and maize starch), talc, titanium dioxide, triethyl citrate.

What REPIGUT looks like and contents of the pack

REPIGUT 20 mg:

Light pink coloured oval shaped, bevel edged tablets debossed with 'H' on one side and '186' on the other side.

REPIGUT 40 mg:

Pink coloured oval shaped, bevel edged tablets debossed with 'H' on one side and '187' on

the other side.

REPIGUT 20 mg and 40 mg tablets are packed in following packs:

Aluminum – Aluminum blisters

Alu-Alu blister pack using aluminium foil with heat seal lacquer and cold formable blister aluminium foil. The blister strips will be packed in an outer carton.

Blisters of 7 tablets packed in 70 (7 x 10) or 126 (7 x 18) tablet pack sizes.

Blisters of 10 tablets packed in 30 (10 x 3) tablet pack size.

Holder of Certificate of Registration

Pharma-Q Holdings (Pty) Ltd

50 Commando Road

Industria West

Johannesburg

2093

This leaflet was last revised in

07 August 2024

Registration numbers

REPIGUT 20 mg: 480550

REPIGUT 40 mg: 480551

Access to the corresponding Professional Information

To be confirmed.