PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

OMEZ 10/20/40, capsules

Omeprazole

Contains sugar (mannitol)

Each 10 mg capsule contains 59 mg of mannitol.

Each 20 mg capsule contains 118 mg of mannitol.

Each 40 mg capsule contains 236 mg of mannitol.

Read all of this leaflet carefully before you start taking OMEZ

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- OMEZ 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 OMEZ is and what it is used for
2. What you need to know before you take OMEZ
3. How to take OMEZ
4. Possible side effects
5. How to store OMEZ
6. Contents of the pack and other information

1. What OMEZ is and what it is used for

OMEZ belongs to a group of medicines called "proton pump inhibitors". OMEZ works by reducing the amount of acid that your stomach produces.

OMEZ is used to treat the following conditions:

Adults:

- Reflux oesophagitis and gastro-oesophageal reflux disease (GORD), where acid from the stomach escapes into the gullet (a tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Zollinger-Ellison Syndrome, when excess stomach acids are produced due to a growth in the pancreas.
- Indigestion (dyspepsia).
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- Duodenal ulcers which are infected with bacteria called "*Helicobacter pylori*".
  If you have this condition, your doctor may also prescribe antibiotics to treat the infection.
- Gastric and/or duodenal ulcers caused by medicines called non-steroidal anti-inflammatory drugs (NSAIDs).
- For reducing the risk of developing ulcers in patients taking NSAIDs and in patients who have previously had an ulcer and need to continue therapy with a NSAID. In such patients, OMEZ can prevent an ulcer developing by protecting the stomach or duodenum (first part of small intestine) whilst they are taking NSAIDs.

Children:

- For the short-term treatment (up to 3 months) of severe ulcerative reflux oesophagitis, which has not responded to previous medical treatment.
  Severe ulcerative reflux oesophagitis is an inflammation of the oesophagus (gullet), including the development of ulcers on the lining of the gullet, caused by stomach acid flowing back into the gullet.

2. What you need to know before you take OMEZ

Do not take OMEZ:

- if you are hypersensitive (allergic) to omeprazole or any of the other ingredients of OMEZ (listed under Section 6).
- if you are pregnant or breastfeeding.

- if you are taking medicines called nelfinavir and atazanavir.
- if you are taking a medicine called St. John's Wort *(Hypericum perforatum)* used for depression.

Warnings and precautions

Take special care with OMEZ:

OMEZ may hide the symptoms of other diseases.

Therefore, if any of the following happen to you before you start taking OMEZ, or while you are taking it, talk to your doctor straight away:

- You lose a lot of weight for no reason and have problems swallowing.
- You get stomach pain or indigestion.
- You begin to vomit food or blood.
- You pass black, tarry stools (blood-stained faeces).
- You experience severe or persistent diarrhoea, as OMEZ has been associated with an increased risk of infectious diarrhoea.
- You have kidney problems.
- OMEZ can cause a type of kidney problem (acute tubulointerstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including OMEZ, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with OMEZ. Call your doctor right away if you have a decrease in the amount that you urinate or if you have blood in your urine.
- You have liver problems - your doctor may want to reduce your dose.
- You are taking a medicine called atazanavir (see Section 2, Do not use OMEZ).
- You have a problem with Vitamin B_{12} levels in your body.
- You are taking a medicine called clopidogrel.
- You suffer from a condition called osteoporosis (weak bones which are easily broken) or if you are taking medicines called corticosteroids.
- You suffer from tiredness, dizziness, fits and heart problems or if your magnesium levels are low.
- You are taking a medicine called digoxin or other medicines that decrease your magnesium

levels.

- You get a rash or skin reaction, especially after being exposed to the sun, after treatment with OMEZ.
- You are due to have a specific blood test (Chromogranin A).
- You start suffering from stomach infections and runny tummy (diarrhoea).

If you take OMEZ 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.

Use in children

There is only a small amount of experience with the use of OMEZ in children.

Some children with chronic illnesses may require long-term treatment although it is not recommended.

Do not give this medicine to children under 1 year of age or < 10 kg.

Other medicines and OMEZ

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines).

Some medicines may interact with OMEZ.

Before taking OMEZ, tell your doctor if you are using any of the following medicines:

- Clopidogrel (used to treat blood clots) – taking OMEZ capsules together with clopidogrel or 12 hours apart results in a lower concentration of clopidogrel in the blood and increases the risk of blood clotting.
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).
- Warfarin (used to thin the blood) - your doctor may need you to take regular blood tests to check how well your blood can clot.
- Phenytoin (used to treat epilepsy) - your doctor may need you to take blood tests to check your phenytoin blood levels.
- Digoxin (used to treat heart problems).
- Nelfinavir, atazanavir and saquinavir (used to treat HIV infection).

- Tacrolimus (used to prevent rejection of transplanted organs).
- Methotrexate (used to treat certain types of cancer or to control severe psoriasis or rheumatoid arthritis).
- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus).
- Erlotinib (used to treat cancer).
- Cilostazol (used to reduce leg pain caused by poor circulation).
- Clarithromycin (used to treat infections).
- Rifampicin (used to treat tuberculosis).
- St. John's Wort (*Hypericum perforatum*) (used to treat mild depression).

If you are using any of these medicines, you may not be able to take OMEZ, or you may need dosage adjustments or your doctor may need to monitor you carefully for side effects.

OMEZ with food and drink

You can take OMEZ capsules with food or on an empty stomach.

Swallow the capsules whole with a half glass of liquid.

Pregnancy and breastfeeding

Do not take OMEZ capsules if you are pregnant or breastfeeding.

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 receiving this medicine.

Driving and using machines

OMEZ capsules may cause sleepiness / drowsiness and affect your ability to concentrate. These side effects may be worsened by taking OMEZ capsules together with alcohol or other central nervous system depressants (medicines used to slow down brain activity and that may make you sleepy; such as cold or allergy medicine, sleeping pills, muscle relaxers, and medicines for seizures, depression or anxiety). If you are affected, do not drive or use machinery.

OMEZ contains mannitol

OMEZ contains mannitol which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using OMEZ.

3. How to take OMEZ

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

Always take OMEZ exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

It is recommended that you take OMEZ capsules in the morning.

Swallow OMEZ capsules whole with half a glass of liquid.

Do not chew or crush the capsules.

Dosage and frequency

Your doctor will tell you how many capsules to take and how long to take them for.

Recommended dosages for adults

Duodenal ulcer

20 mg once daily for two to four weeks.

If you are not responding to other treatment regimens, 40 mg once daily may be effective.

Prevention of relapse in patients with duodenal ulcer

10 mg once daily.

If necessary, the dose can be increased to 20 to 40 mg once daily.

The above recommended dosage regimens are inclusive of *Helicobacter pylori*-positive duodenal ulcers as part of the eradication programme with appropriate antibiotics.

Gastric ulcer (stomach ulcer) and reflux oesophagitis (heartburn)

20 mg once daily for four to eight weeks.

If you are not responding to other treatment regimens, 40 mg once daily may be effective.

For the long-term management of reflux oesophagitis the recommended dose is 10 mg once daily.

If necessary, the dose can be increased to 20 to 40 mg once daily.

If you suffer from severe or symptomatic recurrent reflux oesophagitis treatment can be continued with OMEZ at a dosage of 20 mg once daily.

Treatment and prevention of stomach ulcers, duodenal ulcers, and symptoms caused by medicines called NSAIDs

20 mg once daily for four to eight weeks.

Symptomatic gastro-oesophageal reflux disease (heartburn)

20 mg daily.

If symptom control has not been achieved after four weeks of treatment with the prescribed daily dose, further investigation by your doctor is recommended.

Zollinger-Ellison Syndrome (excess acid in the stomach caused by a tumour in the pancreas)

60 mg once daily.

The dosage should be adjusted individually and treatment continued as long as your doctor recommends it. With doses above 80 mg daily the dose should be divided and given twice daily.

Recommended dosages for children

Severe ulcerative reflux oesophagitis in children from one year and older

Weight:	Dosage:
10 to 20 kg:	10 mg once daily. If needed increase to 20 mg once daily.
> 20 kg:	20 mg once daily. If needed increase to 40 mg once daily.

If you notice that your symptoms have not improved after four weeks of taking OMEZ, consult with your doctor for further investigations to be carried out.

If you have the impression that the effect of OMEZ is too strong or too weak, talk to your doctor or pharmacist.

If you take more OMEZ than you should

- Blurred vision, confusion, excessive sweating, flushing (redness of skin), headache, general

feeling of being unwell, nausea (queasiness, feeling that one is about to vomit), tiredness, dizziness, stomach pain, depression and increased heart rate can occur.

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

If you forget to take OMEZ

If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten individual dose.

If you stop taking OMEZ

Do not stop taking OMEZ unless your doctor tells you to.

4. Possible side effects

OMEZ can have side effects.

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

If you experience any of the following serious side effects, tell your doctor immediately or go to the nearest hospital casualty department:

- Severe allergic reaction which causes sudden wheezing, difficulty in breathing, swelling of your face, lips, tongue, throat or body, rash, fever, fainting or difficulties in swallowing.
- Reddening of the skin with blisters or peeling. There may be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This may be associated with a high fever and joint pains (this could be "Stevens-Johnson Syndrome", "Toxic Epidermal Necrolysis" or "Erythema Multiforme").
- Fever, severe chills, sore throat, mouth ulcers, bleeding or bruising easily, weakness (you may have a blood disorder).
- Inflammation of the liver (hepatitis) which can cause yellow skin, dark urine and tiredness.

- Symptoms such as severe (bloody or repeated watery) diarrhoea, with or without fever, abdominal pain or tenderness (you may have bowel inflammation caused by a bacterial infection).

Other side effects include:

Frequent side effects:

- Headache (If the headache is severe, it may be necessary to stop treatment with OMEZ).
- Effects on your stomach or gut: Diarrhoea (If the diarrhoea is severe, it may be necessary to stop treatment with OMEZ), constipation, stomach pain or colic, wind (flatulence), non-cancerous (benign) abnormal tissue growth (polyps) in the stomach.
- Feeling sick (nausea) or being sick (vomiting).

Less frequent side effects:

- Blood problems such as a reduced number of white blood cells or platelets. This can cause weakness, bruising or make infections more likely. Changes in blood count include agranulocytosis (lack of white blood cells).
- Low levels of sodium in the blood.
- Seeing, feeling or hearing things that are not there (hallucinations), feeling agitated, confused, aggressive, having trouble sleeping (insomnia).
- Dizziness, feeling sleepy, tingling feelings such as "pins and needles", changes in taste.
- Blurred vision.
- Feeling that everything around you is moving or spinning.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Dry mouth, inflammation on the inside of the mouth, thrush in the gut which is caused by a fungus.
- Changes in blood tests that check how the liver is working, liver failure leading to brain damage.
- Skin rash, itchy skin, lumpy rash (hives), skin sensitivity to light, hair loss.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Muscle or joint pain, muscle weakness, fractures of the hip, wrist or spine,

- Lack of energy, generally feeling unwell.
- Severe kidney problems (interstitial nephritis).
- Enlarged breasts in men.
- Increased sweating, swelling of the legs, ankle, feet, arms.

Frequency of side effect not known:

- Severe type of diarrhoea by a bacteria called *Clostridium difficile*.

  It is a type of bacteria that causes diarrhoea if you have been taking antibiotics.
- If you are on OMEZ for more than three months it is possible that

  your levels of magnesium in the blood may be low.

  Very low levels of magnesium can cause low levels of calcium and potassium. This may cause weakness, being sick (vomiting), headache, tiredness, loss of energy, confusion, disorientation, restlessness, irritability, convulsions, dizziness and cramps.

  Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
- Inflammation in the gut (leading to diarrhoea).
- Sores on the skin and rashes over sun-exposed areas like the face, neck, arms, upper back and shoulders.

If any of these side effects get serious, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important.

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 OMEZ.

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5. How to store OMEZ

Store at or below 25 °C. Protect from light and moisture.

Keep the blisters in the outer carton until required for use.

The containers must be tightly closed.

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

Keep all medicines out of reach and sight of children.

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

The active substance is omeprazole.

OMEZ 10: Each capsule contains omeprazole 10 mg

OMEZ 20: Each capsule contains omeprazole 20 mg

OMEZ 40: Each capsule contains omeprazole 40 mg

The other ingredients are crospovidone, hydroxypropyl methyl cellulose, magnesium stearate, mannitol, meglumine, methacrylic acid co-polymer (Type C), poloxamer, povidone and triethyl citrate. The OMEZ capsule shells contain D&C red #28, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, titanium dioxide, and, in addition the 10 mg and 40 mg capsule shells also contain yellow iron oxide, and the 20 mg capsule shells contain black iron oxide.

What OMEZ looks like and contents of the pack

OMEZ 10: Off-white to pale yellow elliptical to spherical enteric-coated pellets, filled in a hard gelati capsule with opaque lavender coloured cap and opaque yellow coloured body. "Omeprazole 10 mg imprinted with black ink on cap and "R157" imprinted with black ink on body.

OMEZ 20: Off-white to pale yellow elliptical to spherical enteric-coated pellets, filled in a hard gelatin capsule with opaque lavender coloured cap and opaque iron grey coloured body. "Omeprazole 20 mg" imprinted with black ink on cap and "R158" imprinted with black ink on body.

OMEZ 40: Off-white to pale yellow elliptical to spherical enteric-coated pellets, filled in a hard gelatin capsule with opaque yellow coloured cap and opaque purple coloured body. "Omeprazole 40 mg" imprinted with black ink on cap and "R159" imprinted with black ink on body.

OMEZ 10: Blister packaging containing 30 or 100 capsules.

White HDPE bottles containing 30 or 100 capsules.

OMEZ 20: Blister packaging containing 14, 30 or 100 capsules.

White HDPE bottles containing 14, 30, 100 or 1000 capsules.

OMEZ 40: Blister packaging containing 14, 28, 30 or 100 capsules.

White HDPE bottles containing 30, 100 or 500 capsules.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

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This leaflet was last revised in

23 April 2024

Registration numbers

OMEZ 10: 34/11.4.3/0299

OMEZ 20: 34/11.4.3/0300

OMEZ 40: 34/11.4.3/0301

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100

Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website:

http://www.drreddys.co.za

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