PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

OMEZ OTC 20, capsules

Omeprazole

Contains sugar (mannitol)

Each 20 mg capsule contains 118 mg of mannitol.

Read all of this leaflet carefully because it contains important information for you

OMEZ OTC 20 is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use OMEZ OTC 20 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share OMEZ OTC 20 with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet:

1. What OMEZ OTC 20 is and what it is used for
2. What you need to know before you take OMEZ OTC 20
3. How to take OMEZ OTC 20
4. Possible side effects
5. How to store OMEZ OTC 20
6. Contents of the pack and other information

1. What OMEZ OTC 20is and what it is used for

OMEZ OTC 20 belongs to a group of medicines called "proton pump inhibitors".

OMEZ OTC 20 works by reducing the amount of acid that your stomach produces.

OMEZ OTC 20 is used for the temporary, short-term relief of heartburn and high stomach acid levels in adults.

2. What you need to know before you take OMEZ OTC 20

Do not take OMEZ OTC 20:

- if you are hypersensitive (allergic) to omeprazole or any of the other ingredients of OMEZ OTC 20 (listed under Section 6).
- if you are pregnant or breastfeeding.
- if you are taking medicines called nelfinavir and atazanavir.

Warnings and precautions

Take special care with OMEZ OTC 20:

OMEZ OTC 20 may hide the symptoms of other diseases.

Therefore, if any of the following happen to you before you start taking OMEZ OTC 20, 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 OTC 20 has been associated with an increased risk of infectious diarrhoea
- You have kidney problems

  OMEZ OTC 20 can cause a type of kidney problem (acute tubulointerstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including OMEZ OTC 20, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with OMEZ OTC 20. 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, therefore your doctor may want to reduce your dose
- You are taking a medicine called atazanavir (see Section 2, Do not use OMEZ OTC 20)
- 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 OTC 20
- You are due to have a specific blood test (Chromogranin A)
- You start suffering from stomach infections and runny tummy (diarrhoea)

Use in children

There is only a small amount of experience with the use of OMEZ OTC 20 in children.

Other medicines and OMEZ OTC 20

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 OTC 20.

Before taking OMEZ OTC 20, tell your doctor if you are using any of the following medicines:

- Clopidogrel (used to treat blood clots) – Taking OMEZ OTC 20 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 to take regular blood tests to check how well your blood can clot
- Phenytoin (used to treat epilepsy) - Your doctor may need to take blood tests to check your phenytoin

blood levels

- Digoxin (used to treat heart problems)
- Nelfinavir and atazanavir (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)

If you are using any of these medicines, you may not be able to take OMEZ OTC 20, or you may need dosage adjustments or your doctor may need to monitor you carefully for side effects.

OMEZ OTC 20 with food and drink

You can take OMEZ OTC 20 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 OTC 20 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 OTC 20 capsules may cause sleepiness/drowsiness and affect your ability to concentrate. These side effects may be worsened by taking OMEZ OTC 20 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 OTC 20 contains mannitol

OMEZ OTC 20 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 OTC 20.

3. HOW TO TAKE OMEZ OTC 20

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

Always take OMEZ OTC 20 exactly as described in this leaflet or as your doctor or pharmacist or nurse have told you.

Check with your doctor or pharmacist or nurse if you are not sure.

It is recommended that you take OMEZ OTC 20 capsules in the morning.

Swallow OMEZ OTC 20 capsules whole with half a glass of liquid.

Do not chew or crush the capsules.

Dosage:

Take 1 capsule daily for up to 14 days.

Do not use continuously for more than 14 days without consulting a doctor.

If you have the impression that the effect of OMEZ OTC 20 is too strong or too weak, talk to your doctor or pharmacist.

If you take more OMEZ OTC 20 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), 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 OTC 20

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.

4. Possible side effects

OMEZ OTC 20 can have side effects.

Not all side effects reported for OMEZ OTC 20 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OMEZ OTC 20, 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).
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.
- 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 OTC 20).
- Effects on your stomach or gut: Diarrhoea (If the diarrhoea is severe, it may be necessary to stop treatment with OMEZ OTC 20, constipation, abdominal 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).

- Suddenly feeling wheezy or short of breath (bronchospasm).
- Severe kidney problems (interstitial nephritis).
- Changes in blood tests that check how the liver is working; liver inflammation (hepatitis) which may include jaundice which can cause yellow skin, dark urine and tiredness; liver failure leading to brain damage.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- 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).
- Seeing, feeling or hearing things that are not there (hallucinations).
- Feeling agitated, confused or depressed.
- Aggressiveness.
- Trouble sleeping (insomnia).
- Dizziness.
- Feeling sleepy.
- Tingling feelings such as "pins and needles".
- Blurred vision.
- Swelling of the ankles, feet or hands.
- Dry mouth.
- An inflammation on the inside of the mouth.
- Thrush in the gullet.
- Taste changes.
- Skin rash, itchy skin, lumpy rash (hives), skin sensitivity to light.
- Hair loss.
- Muscle or joint pain.
- Lack of energy, generally feeling unwell.
- Enlarged breasts in men.

Frequency of side effect not known:

- Inflammation in the gut (leading to diarrhoea).

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 OTC 20.

5. How to store OMEZ OTC 20

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

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

Store the container well 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.

Each capsule contains omeprazole 20 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 capsule shells contain black iron oxide, D&C red #28, FD&C blue #1, FD&C red #40, FD&C yellow #6,

gelatin, titanium dioxide.

What OMEZ OTC 20 looks like and contents of the pack

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.

Blister packaging containing 14 capsules.

White HDPE bottles containing 14 capsules.

Holder of Certificate of Registration

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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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