PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

Sandoz® Omeprazole 20 (capsules)

Omeprazole

Contains sugar (sucrose 108,04 mg) and mannitol 7,91 mg per capsule

Read all of this leaflet carefully before you start taking SANDOZ OMEPRAZOLE 20

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

1. What SANDOZ OMEPRAZOLE 20 is and what it is used for

The active ingredient in SANDOZ OMEPRAZOLE 20 belongs to the group of medicines called inhibitors of the gastric proton pump. They work by reducing the amount of acid that your stomach produces.

SANDOZ OMEPRAZOLE 20 is used for the treatment of conditions associated with over production of acid in the stomach or acid moving into the oesophagus (throat).

2. What you need to know before you take SANDOZ OMEPRAZOLE 20

Do not take SANDOZ OMEPRAZOLE 20 capsules if:

- You are hypersensitive (allergic) to omeprazole or any of the other ingredients of SANDOZ OMEPRAZOLE 20 capsules (listed in section 6).
- If you are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- You are pregnant or breastfeeding.
- You are taking medicines containing nelfinavir (used for HIV infection), atazanavir or St. John's Wort.

Do not take SANDOZ OMEPRAZOLE 20 if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking SANDOZ OMEPRAZOLE 20.

Warnings and precautions

Talk to your doctor or pharmacist before taking SANDOZ OMEPRAZOLE 20:

SANDOZ OMEPRAZOLE 20 may hide the symptoms of other diseases. Therefore, if any of the following happens to you before you start taking SANDOZ OMEPRAZOLE 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 stools (blood-stained faeces).
- You experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea.
- If you have any liver problems as a reduced dose may be required.
- You have ever had a skin reaction after treatment with a medicine similar to SANDOZ OMEPRAZOLE 20 that reduces stomach acid.
- You are due to have a specific blood test (Chromogranin A).
- SANDOZ OMEPRAZOLE 20 capsules may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents.
- Be aware, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

If you take SANDOZ OMEPRAZOLE 20 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.

Taking a proton pump inhibitor like SANDOZ OMEPRAZOLE 20, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist, or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with SANDOZ OMEPRAZOLE 20. Remember to also mention any other ill-effects like pain in your joints.

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 SANDOZ OMEPRAZOLE 20

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

Do not take SANDOZ OMEPRAZOLE 20 if you are taking a medicine containing nelfinavir or atazanavir (used to treat HIV infection).

Please tell your doctor if you are taking the following medicines:

- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus)
- Erlotinib (used to treat cancer)
- Diazepam (used to treat anxiety, relax muscles or in epilepsy), warfarin or other vitamin K blockers (medicine to thin the blood) or phenytoin (anti-epileptic)
- Cilostazol (used to dilate (widen) the blood vessels in your legs to improve blood circulation for the treatment of a condition called claudication)
- Digoxin (used to treat heart problems)
- Tacrolimus (in cases of organ transplantation)
- Saquinavir (used to treat HIV infection)
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your SANDOZ OMEPRAZOLE 20 treatment
- Rifampicin (used to treat tuberculosis)
- St. John’s wort (*Hypericum perforatum*) (used to treat mild depression)
- Clopidogrel (used to prevent blood clots (thrombi)

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as SANDOZ OMEPRAZOLE 20 to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

Not all the medicines that would interact with SANDOZ OMEPRAZOLE 20 are listed above. Please tell your doctor, pharmacist or healthcare provider about all the medicines you are taking before you start taking SANDOZ OMEPRAZOLE 20.

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 SANDOZ OMEPRAZOLE 20 capsules.
SANDOZ OMEPRAZOLE 20 capsule should not be used in pregnancy.
SANDOZ OMEPRAZOLE 20 capsules should not be used by mother breastfeeding their infants.

Driving and using machines

SANDOZ OMEPRAZOLE 20 capsules may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents.

Be aware, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

SANDOZ OMEPRAZOLE 20 contains sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking SANDOZ OMEPRAZOLE 20.

Sucrose may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take SANDOZ OMEPRAZOLE 20

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

Always take SANDOZ OMEPRAZOLE 20 capsules exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Dosage and frequency:

SANDOZ OMEPRAZOLE 20 capsules are recommended to be given in the morning and swallowed whole with a half glass of liquid. The SANDOZ OMEPRAZOLE 20 capsules should not be chewed or crushed.

For treatment ulcers in the upper part of the intestines (duodenal ulcer) the usual dose is one capsule (20 mg) daily for 2 to 4 weeks.

For the prevention of relapse with duodenal ulcer: 10 mg once daily. If necessary the dose can be increased to 20 or 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.

For the treatment of stomach ulcer (gastric ulcer) and reflux oesophagitis the usual dose is one capsule (20 mg) once daily for 4 to 8 weeks.

For the treatment and prevention of stomach ulcers, duodenal ulcers and associated symptoms caused by NSAID's (if you have previously had trouble with an ulcer and need to continue taking NSAID's) the only recommended dose is one capsule (20 mg) daily.

For the treatment of heartburn, the usual dose is one capsule (20 mg) daily for 4 weeks.

For the treatment of excess acid in the stomach caused by a tumour in the pancreas (Zollinger-Ellison syndrome), the normal starting dose is three capsules (60 mg) daily. If the dose is more than 80 mg a day, half the dose should be taken in the morning and half at night.

Dosages in children:

There is very limited experience with the use of SANDOZ OMEPRAZOLE 20 capsules in 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 symptom control has not been achieved after four weeks of treatment with the prescribed daily dose, further investigation is recommended.

If you take more SANDOZ OMEPRAZOLE 20 than you should

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 SANDOZ OMEPRAZOLE 20

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

If you stop taking SANDOZ OMEPRAZOLE 20

Do not stop taking SANDOZ OMEPRAZOLE 20 just because you feel better. Take it for as long as your doctor has prescribed the treatment. If you stop taking your capsules too soon, your symptoms may return.

4. Possible side effects

SANDOZ OMEPRAZOLE 20 can have side effects.

Not all side effects reported for SANDOZ OMEPRAZOLE 20 capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SANDOZ OMEPRAZOLE 20 capsules, please consult your health care provider for advice.

If you notice any of the following rare but serious side effects, stop taking SANDOZ OMEPRAZOLE 20 and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- 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 (SJS)’ or ‘Toxic Epidermal Necrolysis (TEN)’.
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

The frequent side effects are:

- Headache.
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).
- Benign polyps in the stomach.
- Colic.

Less frequent side effects are:

- Swelling of the feet and ankles.
- Disturbed sleep (trouble falling asleep or staying asleep through the night) (insomnia).
- Dizziness, tingling feelings such as “pins and needles”.
- Feeling sleepy.
- Spinning feeling (vertigo).
- Changes in blood tests that check how the liver is working.
- Taste disturbances.
- Sensitivity to light.
- Skin blisters, erythema multiforme, itchy skin.
- Peripheral oedema.
- Blurred vision.
- Raised liver enzymes and increased sweating.
- Benign reversible gastric glandular cysts.
- Skin rash, lumpy rash (hives) and itching skin.
- Generally feeling unwell and lacking energy.
- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing.
- Reversible mental confusion.
- Aggression.
- Hallucinations.
- Malaise and parasthaesias.
- Asthenia, joint pains (arthralgia) and muscle pains (myalgia).
- Dry mouth, stomatitis.
- Oesophageal candidiasis.
- Acid regurgitation.
- Increased gastro-intestinal bacteria.

- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Swelling which is similar to hives.
- Hair loss (alopecia).
- Metabolic condition.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- An inflammation of the inside of the mouth.
- An infection called “thrush” which can affect the gut and is caused by a fungus.
- Inflammation of the nephrons in the kidneys (interstitial nephritis).
- The abnormal development of large mammary glands in males resulting in breast enlargement (gynaecomastia).
- Swelling and inflammation of the liver with or without jaundice which can cause yellow skin, dark urine, and tiredness (hepatitis).
- Skin rash on exposure to sunshine.
- Hepatic encephalopathy.
- Hypersensitivity with rapidly progressing.
- Changes in blood count including agranulocytosis (lack of white blood cells).
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- 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 (SJS), Toxic Epidermal Necrolysis (TEN))
- Muscle weakness.

The frequency of the following side effects are unknown:

- Inflammation in the gut (leading to diarrhoea).
- If you are on SANDOZ OMEPRAZOLE 20 for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
- Rash, possibly with pain in the joints.

SANDOZ OMEPRAZOLE 20 may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a severely reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medicine at this time.

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 SANDOZ OMEPRAZOLE 20. Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store SANDOZ OMEPRAZOLE 20

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Store in the original package to protect from moisture.

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 SANDOZ OMEPRAZOLE 20 contains

Each SANDOZ OMEPRZOLE 20 capsule contains 20 mg omeprazole in a gastro-resistant formulation.

Excipients: Anhydrous disodium phosphate, hypromellose (E464), mannitol (E421), sodium laurilsulfate (sol. 2,5 %) and sugar spheres (maize starch, sucrose).

Gastro-resistant layer: Macrogol 6000, methacrylic acid-ethyl acrylate copolymer (1:1), polysorbate 80 (E433), talc (553b) and titanium dioxide (E171; CI=77891).

Capsule shell: Gelatine, quinoline yellow (E104, CI=47005) and titanium dioxide (E171; CI=77891).

What SANDOZ OMEPRAZOLE 20 looks like and contents of the pack

Hard gelatine capsules of size 2, opaque yellow cap, opaque yellow body, containing off-white (ivory) to cream-white spherical microgranules.

Packs of 15, 28, 30 or 50 capsules in HDPE bottles with silica gel desiccant contained in the polypropylene lid.

Packs of 15, 28, 30 or 50 capsules in thermoformed blisters composed of aluminium/aluminium.

The HDPE bottle or blisters are packed into printed cardboard carton together with the enclosed leaflet.

Not all packs may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

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Jukskei View

Midrand

2090

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Access to the corresponding Professional Information

Not applicable.

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