PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROBITOR 20 (capsules)

Omeprazole

Contains sugar (sucrose 43,350 mg)

Read all of this leaflet carefully before you start taking PROBITOR 20 capsules

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

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

1. What PROBITOR 20 is and what it is used for

PROBITOR 20 contains the active substance omeprazole. It belongs to a group of medicines called ‘proton pump inhibitors’. They work by reducing the amount of acid that your stomach produces.

2. What you need to know before you take PROBITOR 20

Do not take PROBITOR 20:

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

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

Warnings and precautions

Talk to your doctor or pharmacist before taking PROBITOR 20.

PROBITOR 20 may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking PROBITOR 20 or while you are taking it, talk to your doctor straight away:

- If you lose a lot of weight for no reason and have problems swallowing.
- If you get stomach pain or indigestion.
- If you begin to vomit food or blood.
- If you pass black stools (blood-stained faeces).
- If you experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea.
- If you have severe liver problems.
- If you have ever had a skin reaction after treatment with a medicine similar to PROBITOR 20 that reduces stomach acid.

- If you are due to have a specific blood test (Chromogranin A).

If you take PROBITOR 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 PROBITOR 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 PROBITOR 20. Remember to also mention any other ill-effects like pain in your joints.

When taking PROBITOR 20 capsules, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating doctor.

Other medicines and PROBITOR 20

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

Do not take PROBITOR 20 if you are taking a medicine containing nelfinavir (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)
- Digoxin (used to treat heart problems)
- Diazepam (used to treat anxiety, relax muscles or in epilepsy)
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking PROBITOR 20
- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking PROBITOR 20
- Rifampicin (used to treat tuberculosis)
- Atazanavir (used to treat HIV infection)
- Tacrolimus (in cases of organ transplantation)
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)
- Cilostazol (used to treat intermittent claudication)
- Saquinavir (used to treat HIV infection)
- Clopidogrel (used to prevent blood clots (thrombi))
- Erlotinib (used to treat cancer)
- 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 PROBITOR 20 treatment.

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as PROBITOR 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 PROBITOR 20 are listed above. Please tell your doctor, pharmacist or healthcare provider about all the medicines you are taking before you start taking PROBITOR 20.

PROBITOR 20 with food, drink and alcohol

The capsule should be swallowed whole with a glass of water. Do not open the capsule. Do not crush, break or chew the capsule contents. The capsule can be taken with food or on an empty stomach in the morning.

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before taking PROBITOR 20.

PROBITOR 20 capsules should not be used in pregnancy. PROBITOR 20 capsules should not be used by mothers breastfeeding their infants.

Driving and using machines

PROBITOR 20 may cause drowsiness and impaired concentration. Do not drive or operate any machinery before you know how PROBITOR 20 affects you.

PROBITOR 20 contains sucrose

PROBITOR 20 contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take PROBITOR 20.

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

3. How to take PROBITOR 20

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

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

Dosage and frequency:

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

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

To prevent the duodenal and stomach ulcers from coming back: 10 mg once daily. If necessary the dose can be increased to 20 to 40 mg once daily.

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 (Non-Steroidal Anti-Inflammatory Drugs). The 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 growth 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:

Severe ulcerative reflux oesophagitis in children from one year and older:

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

If symptom control has not been achieved after 4 weeks of treatment with the prescribed daily dose, further investigation is recommended.

If you take more PROBITOR 20 than you should

In the event of an overdosage you may experience blurred vision, confusion, flushing, headache, dizziness, sweating, blushing, feeling unwell and tired (malaise), fast heart beat (tachycardia), depression, apathy (feeling like you do not care), stomach pain, diarrhoea, vomiting and nausea.

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

If you forget to take PROBITOR 20

If you missed a dose, take it as soon as you remember. If it is almost time for you next dose, skip the missed dose and continue to take the capsule at the usual time. Do not take a double or larger dose to make up for the forgotten individual doses.

4. Possible side effects

PROBITOR 20 can have side effects.

Not all side effects reported for PROBITOR 20 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PROBITOR 20, please consult your doctor, pharmacist or other healthcare provider for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

The following side effects have occurred frequently:

- Diarrhoea
- Constipation
- Nausea
- Vomiting
- Wind and abdominal pain or colic
- Headache

- Feelings of motion when one is stationary (vertigo)
- Dizziness
- A state of near-sleep or a strong desire for sleep and trouble falling asleep or staying asleep through the night.

The following side effects have occurred less frequently:

- Taste disturbances
- Sensitivity to light
- Skin blisters
- Erythema multiforme
- Itchy skin
- Peripheral oedema
- Blurred vision
- Raised liver enzymes
- Increased sweating
- Benign reversible gastric glandular cysts
- Skin rash and itching
- Reversible mental confusion
- Hallucinations
- Malaise
- Paraesthesia
- Asthenia
- Arthralgia
- Myalgia
- Aggression
- Dry mouth
- Stomatitis
- Oesophageal candidiasis

- Acid regurgitation
- Increased gastro-intestinal bacteria
- Abnormally low level of all blood cells
- Abnormally low amount of platelets
- Failure of the bone marrow to make enough white blood cells (neutrophils)
- Leucopoenia abnormally low number of white blood cells
- Swelling which is similar to hives
- Toxic epidermal necrolysis
- Stevens-Johnson syndrome
- Alopecia
- Metabolic condition
- Bronchospasm
- Agitation
- Fever and depression
- Interstitial nephritis (inflammation of the nephrons in the kidneys), Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness.
- The abnormal development of large mammary glands in males resulting in breast enlargement (gynaecomastia)
- Swelling and inflammation of the liver with or without jaundice (hepatitis)
- Hepatic encephalopathy
- Hypersensitivity with rapidly progressing, life-threatening allergic reaction and fever (anaphylaxis) and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome.
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalized exanthematous pustulosis).

The frequency of the following side effects are unknown:

- Inflammation in the gut (leading to diarrhoea).
- If you are on PROBITOR 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.

PROBITOR 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 PROBITOR 20. Suspected side effects can also be reported directly to the HCR via the link: pvi1j.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

5. How to store PROBITOR 20

Do not store above 25 °C. Store in the original packaging in order to protect from light and moisture.

Do not store your medicine in the bathroom.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use the capsules after the expiry date printed on the container or label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

Active ingredient: each capsule contains 20 mg omeprazole in a formulation that is not affected by stomach acid.

Inactive ingredients:

Gelatine, hypromellose, magnesium oxide heavy, methacrylic acid – ethyl achrylate copolymer 1:1 dispersion, povidone K25, sodium lauryl sulphate, sugar spheres (sucrose), talc and triethyl citrate.

Contains sugar (sucrose 43,350 mg).

What PROBITOR 20 looks like and contents of the pack

PROBITOR 20 is a white capsule filled with almost white to light brown pellets.

PROBITOR 20 is packaged in HDPE plastic bottles with polypropylene or CRC polypropylene screw caps with induction heat seal liner and 1 g silica gel capsules or in aluminium blisters, packed in cardboard cartons in packs of 14, 28, 30, 56 and 60 capsules.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

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Jukskei View

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Access to the corresponding Professional Information

Not applicable.

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