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TOPZOLE® PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

TOPZOLE® 20, Pantoprazole sodium 20 mg, Enteric-coated Tablets

TOPZOLE® 40, Pantoprazole sodium 40 mg, Enteric-coated Tablets

Excipient with known effect (**TOPZOLE® 20,** Enteric-coated Tablets**):**

Each tablet contains 21,33 mg of mannitol and 3,40 mg sodium.

Excipient with known effect (**TOPZOLE® 40,** Enteric-coated Tablets**):**

Each tablet contains 42,70 mg of mannitol and 6,79 mg of sodium

Read all of this leaflet carefully before you start taking TOPZOLE® because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

TOPZOLE® 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 TOPZOLE® is and what it is used for

2. What you need to know before you take TOPZOLE®

3. How to take TOPZOLE®

4. Possible side effects

5. How to store TOPZOLE®

6. Contents of the pack and other information

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1. What TOPZOLE® is and what TOPZOLE® is used for

- The active substance:

TOPZOLE® 20 - Each tablet contains 20 mg pantoprazole.

TOPZOLE® 40 - Each tablet contains 40 mg pantoprazole.

TOPZOLE® is used to treat certain conditions in which there is too much acid in the stomach. It is used to treat duodenal and gastric ulcers, reflux oesophagitis and Zollinger-Ellison Syndrome. It is indicated for symptomatic improvement (e.g. heartburn, contents of the stomach which washes back into the oesophagus, pain on swallowing) and healing of mild gastro-oesophageal reflux disease.

TOPZOLE® is indicated for the prevention of gastroduodenal lesions, heartburn and indigestion symptoms caused by non-selective non-steroidal anti-inflammatory drugs (NSAID's), i.e., medicines other than cortisone used to treat pain and inflammation.

TOPZOLE® works by decreasing the amount of acid produced by the stomach.

2. What you need to know before you take TOPZOLE®

Do not take TOPZOLE® if you:

- if you are hypersensitive (allergic) to pantoprazole or any of the other ingredients.
- if you are taking atazanavir or nelfinavir (an anti-HIV medicine)
- if you have serious liver problems

Warnings and precautions

- If you have severe liver problems. Please tell your doctor if you have ever had problems with your liver in the past. Your doctor will check your liver enzymes more frequently, especially when you are taking **TOPZOLE®** as a long-term treatment. In the case of a rise of liver enzymes the treatment should be stopped.
- If you have reduced body stores or risk factors for reduced vitamin B_{12} and receive long-term treatment with pantoprazole. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B_{12}. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of Vitamin B_{12}:

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- Extreme tiredness or lack of energy
- Pins and needles
- Sore or red tongue, mouth ulcers
- Muscle weakness
- Disturbed vision
- Problems with memory, confusion, depression

- If you are taking HIV protease inhibitors such as atazanavir or nelfinavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.
- Taking a proton pump inhibitor like pantoprazole, 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 (reduced bone density) or if you have been told that you are at risk of getting osteoporosis (for example, if you are taking steroids).
- If you are on **TOPZOLE®** 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, 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.
- If you have ever had a skin reaction after treatment with a medicine similar to **TOPZOLE®** that reduces stomach acid.
- 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 **TOPZOLE®**. Remember to also mention any other ill-effects like pain in your joints.
- Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and erythema multiforme, have been reported in association with pantoprazole treatment. Stop using pantoprazole and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- If you are due to have a specific blood test (Chromogranin A).
- if you:
  - are taking tablets containing ketoconazole, used to treat fungal infections of the skin and nails. This is because **TOPZOLE®** may increase or decrease the effect of ketoconazole by altering the amount that gets in your body.

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- think you have signs of stomach cancer. These include persistent weight loss, dark stools, loss of appetite, feeling full or a lump in your stomach.
- experience severe and/or persistent diarrhoea, as **TOPZOLE®** has been associated with a small increase in infectious diarrhoea.

Elderly patients

TOPZOLE® has not been shown to cause different side effects or problems in older people than it does in younger adults.

Kidney and liver disease

No dosage adjustment is required in the presence of kidney disease.

Your doctor will advise you on the use of **TOPZOLE®** if you have liver disease. You may not use **TOPZOLE®** in severe liver disease.

Taking TOPZOLE® with food and drink:

TOPZOLE® tablets may be taken with food or on an empty stomach.

Other medicines and TOPZOLE®

If you are taking other medicines on a regular basis, including complementary or traditional medicines, consult your doctor, pharmacist or other healthcare professional for advice, as these medicines may cause undesirable interactions. Other medicines that reduce stomach acid can be taken at the same time as **TOPZOLE®.**

Some of the medicines that can be affected by taking **TOPZOLE®** include: Medicines to thin your blood, such as warfarin. **TOPZOLE®** may alter the effect of these medicines so your doctor may monitor how well your blood clots.

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TOPZOLE® may decrease the amount of atazanavir, which is used for the treatment of HIV infection, that gets into your body. **TOPZOLE®** may increase the levels of methotrexate (high doses used in the treatment of certain cancers) and possibly lead to methotrexate toxicities.

Pregnancy, breast-feeding and fertility

Safety in pregnancy and during breast-feeding has not been established. If you are pregnant or breast-feeding your baby while taking **TOPZOLE®**, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery

Your treatment may influence your ability to drive or operate machines. If you feel unwell during treatment or experience side effects like dizziness or disturbed vision, you should not drive or operate machines,

TOPZOLE® contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

TOPZOLE® contains Mannitol

You should not take **TOPZOLE®** If you have rare hereditary condition of mannitol intolerance.

3. HOW TO TAKE TOPZOLE®

Always take **TOPZOLE®** exactly as your doctor has instructed. Check with your doctor or pharmacist if you are unsure.

The once daily dose of **TOPZOLE®** should be taken in the morning.

The tablet should be swallowed whole with a little water either before or during breakfast. Do not crush, break or chew the tablet.

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Duodenal ulcer

The recommended dose is **40 mg TOPZOLE®** once daily for 2 to 4 weeks.

Gastric ulcer and reflux oesophagitis

The recommended dose is one **40 mg TOPZOLE® tablet** per day for 4 to 8 weeks.

Zollinger-Ellison Syndrome

The starting dose is usually one **40 mg TOPZOLE®** tablet taken twice dailyy. Your doctor will advise you on how to take the medicine.

Mild gastro-oesophageal reflux disease

The dose is one **20 mg TOPZOLE®** tablet per day for 4 to 8 weeks. In patients with healed reflux disease, re-occurring symptoms can be controlled using **20 mg TOPZOLE®** when needed.

Long-term treatment and to prevent gastro-oesophageal reflux disease starting up again

For a long period of treatment a dose of one **20 mg TOPZOLE®** tablet per day is advised, increasing to one **40 mg TOPZOLE®** tablet per day if the **gastro-oesophageal reflux disease** starts again. After healing, the dose can once again be reduced to 20 mg daily.

One **20 mg TOPZOLE®** tablet per day can be taken together with certain anti-inflammatory medicines, to prevent

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heartburn, indigestion and possible injury to the stomach and intestines.

If you take more TOPZOLE® than you should:

In the event of an overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take TOPZOLE®:

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten doses.

4. Possible side effects

TOPZOLE® can have side effects.

Check with your doctor as soon as possible if any of the following side effects occur:

If you get any of the following side effects, stop taking these tablets and tell your doctor immediately, or contact the casualty department at your nearest hospital:

- Serious allergic reactions (frequency rare: may affect up to 1 in 1,000 people): swelling of the tongue and/or throat, difficulty in swallowing, hives (nettle rash), difficulties in breathing, allergic facial swelling (Quincke's oedema / angioedema), severe dizziness with very fast heartbeat and heavy sweating.

- Serious skin conditions (frequency not known: frequency cannot be estimated from the available data): you may notice one or more of the following - blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals, or skin sensitivity/rash, particularly in areas of skin exposed to light/the sun. You may also have joint pain or flu-like symptoms, a fever, swollen glands (e.g. in the armpit) and blood tests may show changes in certain white blood cells or liver enzymes.

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- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).

- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

- Other serious conditions (frequency not known): yellowing of the skin or whites of the eyes (severe damage to liver cells, jaundice) or fever, rash, and enlarged kidneys sometimes with painful urination, and lower back pain (serious inflammation of the kidneys), possibly leading to kidney failure.

Other side effects are:

- Common (may affect up to 1 in 10 people)

Benign polyps in the stomach

- Uncommon (may affect up to 1 in 100 people)

Headache; dizziness; diarrhoea; feeling sick, vomiting; bloating and flatulence (wind); constipation; dry mouth; abdominal pain and discomfort; skin rash, exanthema, eruption; itching; feeling weak, exhausted or generally unwell; sleep disorders; fracture in the hip, wrist or spine.

- Rare (may affect up to 1 in 1,000 people)

Distortion or complete lack of the sense of taste; disturbances in vision such as blurred vision; hives; pain in the joints; muscle pains; weight changes; raised body temperature; high fever; swelling of the extremities (peripheral oedema); allergic reactions; depression; breast enlargement in males.

- Very Rare (may affect up to 1 in 10,000 people)

Disorientation.

- Not known (frequency cannot be estimated from the available data)

Hallucination, confusion (especially in patients with a history of these symptoms); feeling of tingling, prickling, pins and needles, burning sensation or numbness, rash, possibly with pain in the joints, inflammation in the large bowel, that causes persistent watery diarrhoea.

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Side effects identified through blood tests:

- Uncommon (may affect up to 1 in 100 people)

an increase in liver enzymes.

- Rare (may affect up to 1 in 1,000 people)

an increase in bilirubin; increased fat levels in blood; sharp drop in circulating granular white blood cells, associated with high fever.

- Very Rare (may affect up to 1 in 10,000 people)

a reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; a reduction in the number of white blood cells, which may lead to more frequent infections; coexisting abnormal reduction in the number of red and white blood cells, as well as platelets.

- Not known (frequency cannot be estimated from the available data)

decreased level of sodium, magnesium, calcium or potassium in blood (see section 2).

Some side effects may disappear during treatment as your body adjusts to the medicine. These do not need medical attention.

Not all side effects reported for **TOPZOLE®** are included in this leaflet. Should your general health worsen while taking **TOPZOLE®**, please consult your doctor, pharmacist or other healthcare professional for advice.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or health care provider. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Additionally, suspected adverse reactions can be reported to AE.southafricassa@takeda.com or on the 24 hours contact number: 082 525 3040. By reporting side effects, you can help provide more information on the safety of this

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5. How to store TOPZOLE®

Store at or below 30 ˚C.

Protect the medicine from light and moisture.

Do not store in the bathroom.

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

Return all unused medicine to your pharmacist for correct disposal.

Do not throw unused medicine down drains or toilets.

KEEP ALL MEDICINES OUT OF THE SIGHT AND REACH OF CHILDREN.

6. Contents of the pack and other information

What TOPZOLE® contains

- The active substance is pantoprazole.
- The other ingredients are:

Calcium stearate, crospovidone, hypromellose, mannitol, methacrylic acidethylacrylate-copolymer (1:1), polysorbate 80, povidone K25, povidone K90, propylene glycol, sodium carbonate, sodium laurilsulphate, titanium dioxide E171, triethyl citrate, yellow ferric oxide.

The tablet-marking contains small amounts of the following: shellac, iron oxides, soya lecithin, titanium dioxide E171 and antifoam DC1510.

What TOPZOLE® looks like and contents of the pack

TOPZOLE® 20: Yellow, oval, biconvex enteric-coated tablet with a white to off-white core, imprinted "P20" on one side.

TOPZOLE® 40: Yellow, oval, biconvex enteric-coated tablet, with a white to off-white core, imprinted "P40" on one side.

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TOPZOLE® 20: Tablets in white plastic bottle fitted with grey screw closure and attached bellows-type spacer, in quantities of 28 tablets or in printed silver aluminium foil blister packs of 28 tablets.

TOPZOLE® 40: Tablets in white plastic bottle fitted with grey screw closure and attached bellows-type spacer, in quantities of 14 and 28 tablets or in printed silver aluminium foil blister packs of 14 and 28 tablets.

REGISTRATION NUMBER

TOPZOLE® 20: 38/11.4.3/0061

TOPZOLE® 40: 38/11.4.3/0060

HOLDER OF CERTIFICATE OF REGISTRATION

TAKEDA (Pty) Ltd

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