PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PRAZANT 20 and 40 (20 mg and 40 mg) enteric coated tablets

Pantoprazole sodium sesquihydrate

PRAZANT 20 contains sugar (53,06 mg mannitol)

PRAZANT 40 contains sugar (106,12 mg mannitol)

PRAZANT 20 and PRAZANT 40 contains less than 1 mmol sodium (23 mg) per tablet which means that it is essentially 'sodium-free'.

Read all of this leaflet carefully before you start taking PRAZANT:

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

1. What PRAZANT is and what it is used for

PRAZANT is a selective "proton pump inhibitor", a medicine which reduces the amount of acid produced in your stomach. It is used for treating acid-related diseases of the stomach and intestine.

PRAZANT 20 is used for treating:

- Mild reflux oesophagitis (inflammation of the oesophagus, a tube that runs from throat to the stomach), and control of recurring symptoms in patients with healed reflux disease using an on-demand regimen.
- Long-term treatment and prevention of relapse reflux disease.
- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Pantoprazole can also be used to stop stomach ulcers from forming if you are taking NSAIDs.

PRAZANT 40 is used for treating:

- Reflux oesophagitis. An inflammation of your oesophagus (the tube which connects your throat to your stomach) accompanied by the regurgitation of stomach acid.
- An infection with a bacterium called *Helicobacter pylori* in patients with duodenal ulcers and stomach ulcers in combination with two antibiotics (Eradication therapy).
- Stomach and duodenal ulcers.
- Zollinger-Ellison-Syndrome a digestive disorder that results in too much gastric acid.

2. What you need to know before you take PRAZANT

Do not take PRAZANT:

- if you are hypersensitive (allergic) to pantoprazole or to any of the other ingredients of PRAZANT (see list under section 6).
- if you have serious liver problems.
- if you are taking medicines for HIV such as atazanavir or nelfinavir (antiretrovirals): These medicines may not work as well against your HIV infection if you take them with PRAZANT.
- PRAZANT must not be given to children as it is not known if it is safe and effective for them.

Warnings and precautions

Tell your doctor or healthcare professional before taking PRAZANT:

Take special care with PRAZANT

- If you have severe liver problems or if you ever had problems with your liver in the past. Your doctor will check your liver enzymes more frequently, especially when you are taking PRAZANT 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 B12 and receive pantoprazole long-term treatment, as pantoprazole may lead to a reduced absorption of vitamin B12.
- 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.
- If you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis). 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.
- If you are on PRAZANT 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 that reduces stomach acid such as PRAZANT.
- If you get a rash on your skin, especially in areas exposed to the sun, you may need to stop your treatment with PRAZANT. Remember to also mention any other ill-effects like pain in your joints.
- If you are due to have a specific blood test (Chromogranin A).

Tell your doctor immediately if you notice any of the following symptoms:

- an unintentional loss of weight
- vomiting, particularly if repeated
- vomiting blood; this may appear as dark coffee grounds in your vomit
- you notice blood in your stools; which may be black or tarry in appearance
- difficulty in swallowing or pain when swallowing
- chest pain
- stomach pain
- you look pale and feel weak (anaemia)
- severe and/or persistent diarrhoea, as PRAZANT has been associated with a small increase in infectious diarrhoea.
- blood in the urine, fever, urinating less than normal

Your doctor may decide that you need some tests to rule out malignant disease because pantoprazole also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.

If you take PRAZANT 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.

Children and adolescents

PRAZANT must not be given to children as it is unknown if it is safe and effective for them *(see "Do not take PRAZANT")*.

Other medicines and PRAZANT

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

PRAZANT may influence the effectiveness of other medicines, so tell your doctor if you are taking:

- Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer) because PRAZANT may stop these and other medicines from working properly.
- Warfarin and phenprocoumon, which affect the thickening, or thinning of the blood. You may need further checks.
- Medicines used to treat HIV-infection, such as atazanavir or nelfinavir.
- Methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) – if you are taking methotrexate your doctor may temporarily stop your PRAZANT treatment because pantoprazole can increase levels of methotrexate in the blood.
- Fluvoxamine (used to treat depression and other psychiatric diseases) – if you are taking fluvoxamine your doctor may reduce the dose.
- Mycophenolate mofetil – pantoprazole may reduce exposure to the active metabolite, mycophenolic acid.
- Rifampicin – medicine used to treat tuberculosis.
- St John's Wort – medicine used for depression.

PRAZANT with food and drink

PRAZANT should be taken either before or during breakfast without chewing or breaking them, swallow them whole with some water.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist, or other healthcare provider for advice before taking this medicine.

Safety in pregnancy and during lactation is unknown.

Driving and using machines

Pantoprazole does not adversely affect the ability to drive or use machines, however, adverse drug reactions such as dizziness and visual disturbances may occur. If affected, you should not drive or operate machines.

PRAZANT contains sodium

PRAZANT 20 and PRAZANT 40 contains less than 1 mmol sodium (23 mg) per tablet which means that it is essentially 'sodium-free'.

3. How to take PRAZANT

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

Always take PRAZANT exactly as your doctor or pharmacist has told. Check with your doctor or pharmacist if you are not unsure.

The recommended dose is PRAZANT 20 mg to PRAZANT 40 mg once a day depending on your condition. Your doctor will prescribe an appropriate dose according to your condition.

PRAZANT tablets should be taken in the morning, swallowed whole with little water either before or during breakfast.

The enteric coated tablet should not be crushed because the coating prevents pH sensitive degradation in the gut.

Use in children and adolescents

These tablets are not recommended for use in children due to limited data on safety and efficacy.

If you take more PRAZANT than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. There are no known symptoms of overdose however as in any case of overdosage, treatment should be symptomatic and supportive measures should be utilised.

If you forget to take PRAZANT

Do not take a double dose to make up for a forgotten dose. Take your next normal dose at the usual time.

If you stop taking PRAZANT

Do not stop taking these tablets without first talking to your doctor or pharmacist. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

PRAZANT can have side effects.

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

If any of the following happens to you, stop taking PRAZANT and tell your doctor immediately, or go to the casualty department at your nearest hospital:

- severe allergic reaction to PRAZANT with swelling of the mouth, tongue, or face and/or throat,
- difficulty to breathe or swallow,
- red lumpy skin rash (hives)
- dizziness which may result in collapse

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PRAZANT. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you experience itching, right upper-belly pain, dark urine, yellow skin/eyes (jaundice), and unexplained flu-like symptoms (symptoms of liver damage that can lead to liver failure).
- If you develop severe flu-like symptoms followed by severe skin blisters with redness around them, or a peeling rash, hives and/or mouth sores: These are symptoms of Stevens-Johnson syndrome, a sometimes-fatal form of allergic skin disease.
- Any other severe skin eruption or swelling, especially in the face, near the eyes and mouth and sometimes in the throat, causing narrowing and difficulty with breathing that can be fatal.
- Problems with passing urine or if you pass urine more often than usual and develop a fever and generally feel unwell, or if you notice blood in your urine.
- Watery stool/runny tummy that does not go away, stomach pain and fever (See Section 2).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The frequent side effects of PRAZANT are:

- Digestive tract problems such as stomach pain, runny tummy (watery stools), constipation and bloating (gas)
- Headache.

Other less frequent effects include:

- nausea (feeling sick),
- vomiting,
- dry mouth,
- feeling abnormally weak and tired,
- generally feeling unwell,

- swollen hands and feet,
- hypersensitivity (allergic reactions) (see above),
- not seeing clearly,
- blood test results showing increased liver enzymes
- impaired liver function,
- increase of certain fats in the blood (triglycerides, cholesterol),
- increase in bilirubin (formed when red blood cells breakdown),
- weight changes,
- increase in body temperature,
- joint pain,
- muscle pain,
- increased risk of wrist, hip, and spine bone breaks,
- feeling of dizziness or feeling like ‘spinning’,
- taste disorders,
- feeling down,
- not sleeping well,
- feeling confused or baffled,
- inflammation of the small, narrow spaces in the tissue of the kidney that can cause kidney problems,
- decrease in the blood of the number of red, white cells and platelets (pancytopenia), white blood cells (leaukopenia) (may increase the risk of inflammation/infection), platelets (thrombocytopenia) (may increase risk of bruising or bleeding),
- sharp drop in circulating granular white blood cells (agranulocytosis) - an acute disease marked by high fever.
- oversensitivity to sunlight.

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.

5. How to store PRAZANT

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 25 °C in original packaging.
- Do not use after the expiry date printed on the label or carton.
- 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

What PRAZANT contains

The active substance is pantoprazole.

Each PRAZANT 20 tablet contains pantoprazole sodium sesquihydrate equivalent to 20 mg pantoprazole.

Each PRAZANT 40 tablet contains pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole.

The other ingredients are:

Core: Butylated methacrylate copolymer, calcium stearate, mannitol, sodium carbonate anhydrous, sodium starch glycolate (Type A).

Coating: Hypromellose, macrogol / PEG 400, methacrylic acid-ethyl acrylate copolymer dispersion 30 %, propylene glycol, sodium lauryl sulfate, talc, titanium dioxide (E171) and yellow iron oxide (E 172).

What PRAZANT looks like and contents of the pack

PRAZANT 20 is light yellow, elliptical normal biconvex enteric coated tablets.

PRAZANT 40 is dark yellow, elliptical normal biconvex enteric coated tablets.

PRAZANT is packed in either aluminium blister packs or in HDPE containers closed with twist-off polypropylene caps with integrated desiccant (containing silica gel).

Blister packs contain either 7, 14, 28 or 30 tablets.

For PRAZANT 20, the HDPE container contains 15 tablets.

For PRAZANT 40, the HDPE container contains 7 or 250 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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