
SCHEDULING STATUS

S2

PEPTAZOL 20, 20 mg, Enteric coated tablets

Pantoprazole (as sodium sesquihydrate)

Sugar free

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

PEPTAZOL 20 is available without a doctor's prescription, for you to treat heartburn and hyperacidity. Nevertheless, you still need to use PEPTAZOL 20 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PEPTAZOL 20 with any other person.
- Ask your healthcare 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 PEPTAZOL 20 is and what it is used for
2. What you need to know before you take PEPTAZOL 20
3. How to take PEPTAZOL 20
4. Possible side effects
5. How to store PEPTAZOL 20
6. Contents of the pack and other information

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

PEPTAZOL 20 contains pantoprazole. Pantoprazole belongs to a class of medicine called proton pump inhibitors, which reduces stomach acid production.

PEPTAZOL 20 is used for the short-term relief of heartburn and hyperacidity for a maximum of 14 days.

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

Do not take PEPTAZOL 20

- If you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of PEPTAZOL 20 (listed in section 6).
- If you suffer from severe liver disease.
- Safety and efficacy have not been established in children.
- If you are taking atazanavir (a medicine used in the treatment of HIV-infection).

Warnings and precautions

Take special care with PEPTAZOL 20:

- If PEPTAZOL 20 is prescribed by your doctor, he/she may decide that you need some tests to rule out cancer because pantoprazole also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue despite your treatment, further investigations will be considered.
- If you have or develop problems with your kidneys, e.g. difficulty to urinate or blood in your urine, stop taking PEPTAZOL 20 and talk to your doctor or pharmacist (see section 4).
- If you have impaired liver function, you should talk to your doctor before taking PEPTAZOL 20.
- If you have a history of a Vitamin B₁₂ deficiency, as PEPTAZOL 20 may further reduce the absorption of this vitamin.
- If you develop diarrhoea that does not improve, contact your doctor or healthcare professional as soon as possible.
- If you have low levels of magnesium or if you notice any of the following: 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 low levels of potassium and/or calcium in the blood. Your doctor may decide to perform regular blood tests to monitor these levels.

- 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). Taking PEPTAZOL 20, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine.
- If you ever had a skin reaction with medicine similar to PEPTAZOL 20 or if you get a skin reaction while taking PEPTAZOL 20, especially in areas exposed to the sun, tell your doctor as soon as you can. You may have a severe reaction and may need to stop PEPTAZOL 20 treatment. Remember to also mention any other ill-effects like pain in your joints to your doctor (see section 4).
- If you are due to have a specific blood test (Chromogranin A). PEPTAZOL 20 can influence the results of this test.

Children and adolescents

Do not give PEPTAZOL 20 to children, as safety and efficacy have not been established in children below the age of 12 years.

Other medicines and PEPTAZOL 20

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

Tell your doctor or pharmacist if you are taking any of the following as PEPTAZOL 20 may increase or decrease the effect of these medicines:

- Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer), as PEPTAZOL 20 may change their absorption.

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- 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.
 - Methotrexate used to treat rheumatoid arthritis, psoriasis, and cancer.
 - Fluvoxamine used to treat depression and other psychiatric diseases.
 - Rifampicin used to treat infections.
 - St John's wort (*Hypericum perforatum*) used to treat mild depression.

Pregnancy and breastfeeding

You should not take PEPTAZOL 20 if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking PEPTAZOL 20.

Driving and using machines

PEPTAZOL 20 may affect your ability to drive and to use machinery. Possible side effects (see section 4) such as dizziness and disturbances in vision e.g. blurred vision may decrease your ability.

It is not always possible to predict to what extent PEPTAZOL 20 may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which PEPTAZOL 20 affects you.

PEPTAZOL 20 contains tartrazine and sodium

PEPTAZOL 20 contains FD & C Yellow N°5 (tartrazine) which may cause allergic reactions.

PEPTAZOL 20 contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially sodium-free.

3. How to take PEPTAZOL 20

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

Always take PEPTAZOL 20 exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist, or nurse if you are unsure.

The usual dose is one PEPTAZOL 20 tablet per day, for a maximum period of 14 days.

If your symptoms do not improve after 14 days, please consult your doctor as further investigation is recommended.

Swallow the tablet whole, with water in the morning before or during breakfast. Do not crush, break, or chew the tablet.

If you take more PEPTAZOL 20 than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.

If you forget to take a dose of PEPTAZOL 20

If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

PEPTAZOL 20 can have side effects.

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

If any of the following happens, stop taking PEPTAZOL 20 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reaction such as skin rash, itchiness, swelling of the mouth, lips or tongue, or if you experience increased pulse rate or increased sweating.
- Serious skin reaction such as skin rash, itching, blistering, loosening, or peeling of the skin (including slight bleeding), 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).
- Damage to liver cells or jaundice with symptoms such as yellowing of the skin or whites of the eyes.
- Kidney damage with symptoms such as fever, rash, and enlarged kidneys sometimes with painful urination, and lower back pain (serious inflammation of the kidneys), possibly leading to kidney failure.

These are all very serious side effects. If you have them, you may have had a serious reaction to PEPTAZOL 20. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- Headache
- Pain in your stomach, diarrhoea, nausea, vomiting, constipation, flatulence or wind, dry mouth
- Benign polyps in the stomach.

Less frequent side effects

- Blood tests show reduction in the number of blood platelets and/or white cells, which may cause you to bleed or bruise more easily and/or have more infections
- Blood tests show increase liver enzymes, lipids (fat levels) and bilirubin
- Changes in weight
- Sleep disorders, feeling depressed and disorientated
- Dizziness, distortion or complete lack of the sense of taste
- Disturbances in vision such as blurred vision
- Skin hives (urticaria), rash, itching
- Pain in muscles (myalgia), pain in the joints (arthralgia), fracture of the hip, wrist or spine
- Swelling of male breasts (gynaecomastia)
- Increase in body temperature and swelling of hands and feet.

Frequency unknown side effects

- Blood tests show decreased level of sodium, magnesium, calcium or potassium. You may have muscle cramps (spasms).
- Hallucination, confusion (especially if you have a history of these symptoms)
- Inflammation in the large bowel.

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>.

In addition, side-effects can also be reported to info@pharmacorp.co.za.

By reporting side effects, you can help provide more information on the safety of PEPTAZOL 20.

5. How to store PEPTAZOL 20

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in outer unit carton until required for use.
- Do not use after the expiry date stated on the blister / carton.
- Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What PEPTAZOL 20 contains

The active substance is pantoprazole (as sodium sesquihydrate).

Each tablet contains 20 mg of pantoprazole (as sodium sesquihydrate).

The other ingredients are calcium stearate, crospovidone, mannitol, Povidone K 90, sodium carbonate.

Base coating: Opadry QX White (321A180025) (containing glyceryl monocaprylocaprate, polyvinyl alcohol, PEG-Polyvinyl alcohol copolymer, talc).

Enteric coating: Acryl-Eze II White (493Z180022), (containing calcium silicate, methacrylic acid copolymer, poloxamer, sodium bicarbonate, sodium lauryl sulphate, talc, titanium dioxide), simethicone, tartrazine yellow (CI 19140)

Sugar free.

Contains colouring agent as tartrazine yellow.

Each tablet contains 3,02 mg sodium.

What PEPTAZOL 20 looks like and contents of the pack

PEPTAZOL 20 are yellow coloured, circular, biconvex, enteric coated tablets packaged in an OPA-aluminium foil blister containing 14 tablets.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Available on SAHPRA repository website