**APPROVED PATIENT INFORMATION LEAFLET FOR PEPTISEC**

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS: S4**

**PEPTISEC 10, 20 and 40 Hard gelatine gastro-resistant capsules**

**Omeprazole**

PEPTISEC 10 contains sugar (mannitol, 2,5 mg and sucrose, no more than 6,1 mg per capsule).

PEPTISEC 20 contains sugar (mannitol, 5,0 mg and sucrose, no more than 12,3 mg per capsule).

PEPTISEC 40 contains sugar (mannitol, 10,0 mg and sucrose, no more than 24,5 mg per capsule).

**Read all of this leaflet carefully before you start taking PEPTISEC.**

- 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.
- PEPTISEC 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**

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6. Contents of the pack and other information

**1. What PEPTISEC is and what it is used for**

PEPTISEC belongs to a group of medicines called “proton pump inhibitors”. PEPTISEC works by reducing the amount of acid that your stomach produces.

PEPTISEC is used to treat the following conditions:

*Adults:*

- Reflux oesophagitis and gastro-oesophageal reflux disease (GORD), where acid from the stomach escapes into the gullet (a tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Indigestion (dyspepsia).
- Zollinger-Ellison Syndrome, when excess stomach acids are produced due to a growth in the pancreas.
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- Duodenal ulcers which are infected with bacteria called “*Helicobacter pylori*”.
  If you have this condition, your doctor may also prescribe antibiotics to treat the infection.
- Gastric and/or duodenal ulcers caused by medicines called non-steroidal anti-inflammatory drugs (NSAIDs).
- For reducing the risk of developing ulcers in patients taking NSAIDs and in patients who have previously had an ulcer and need to continue therapy with a NSAID. In such patients, PEPTISEC can prevent an ulcer developing by protecting the stomach or duodenum (first part of small intestine) whilst they are taking NSAIDs.

*Children:*

- For the short-term treatment (up to 3 months) of severe ulcerative reflux oesophagitis,

which has not responded to previous medical treatment.

Severe ulcerative reflux oesophagitis is an inflammation of the oesophagus (gullet), including the development of ulcers on the lining of the gullet, caused by stomach acid flowing back into the gullet.

## 2. What you need to know before you take PEPTISEC

**Do not take PEPTISEC:**

- If you are hypersensitive (allergic) to omeprazole or any of the other ingredients of PEPTISEC (listed under Section 6).
- If you are pregnant or breastfeeding.
- If you are taking medicines called nelfinavir and atazanavir.

**Warnings and Precautions**

***Take special care with PEPTISEC:***

Serious skin reactions have occurred in patients taking omeprazole, as contained in PEPTISEC (see also section 4 – **Possible side effects**). The rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin reactions often come after flu-like symptoms such as fever, headache, body ache. The rash may cover large parts of the body with blistering and peeling of the skin, if at any time during the treatment (even after several weeks) you develop a rash or any of these skin symptoms, stop taking this medicine and contact your doctor immediately.

PEPTISEC may hide the symptoms of other diseases.

Therefore, if any of the following happen to you before you start taking PEPTISEC, 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, tarry stools (blood-stained faeces)
- You experience severe or persistent diarrhoea, as PEPTISEC has been associated with an increased risk of infectious diarrhoea
- You have kidney problems
- PEPTISEC can cause a type of kidney problem (acute tubulointerstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including PEPTISEC, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with PEPTISEC. Call your doctor right away if you have a decrease in the amount that you urinate or if you have blood in your urine.
- You have liver problems, therefore your doctor may want to reduce your dose
- You are taking a medicine called atazanavir (see Section 2, Do not use PEPTISEC)
- You have a problem with Vitamin $B_{12}$ levels in your body
- You suffer from a condition called osteoporosis (weak bones which are easily broken) or if you are taking medicines called corticosteroids
- You suffer from tiredness, dizziness, fits and heart problems, which may indicate your magnesium levels are low
- You are taking a medicine called digoxin or other medicines that decrease your magnesium levels
- You get a rash or skin reaction, accompanied by joint pain, especially after being exposed to the sun, after treatment with PEPTISEC
- You are due to have a specific blood test (Chromogranin A)
- You start suffering from stomach infections and runny tummy (diarrhoea)

**Use in children**

There is only a small amount of experience with the use of PEPTISEC in 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 PEPTISEC**

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

Some medicines may interact with PEPTISEC.

Before taking PEPTISEC, tell your doctor if you are using any of the following medicines:

- Clopidogrel (used to treat blood clots) – Taking PEPTISEC capsules together with clopidogrel or 12 hours apart results in a lower concentration of clopidogrel in the blood and increases the risk of blood clotting
- Diazepam (used to treat anxiety, relax muscles or in epilepsy) -Taking PEPTISEC together with diazepam may result in an increased concentration of diazepam in the blood.
- Warfarin (used to thin the blood) - Your doctor may need to take regular blood tests to check how well your blood can clot. Taking PEPTISEC together with warfarin may result in an increased concentration of warfarin in the blood.
- Phenytoin (used to treat epilepsy) - Your doctor may need to take blood tests to check your phenytoin blood levels. Taking PEPTISEC together with phenytoin may result in an increased concentration of phenytoin in the blood.
- Digoxin (used to treat heart problems). Taking PEPTISEC together with digoxin may result in an increased concentration of digoxin in the blood.
- Nelfinavir, atazanavir and saquinavir (used to treat HIV infection). Taking PEPTISEC together with nelfinavir and atazanavir may result in a decreased effect of these medicines. Concomitant use should therefore be avoided.

  Taking PEPTISEC together with saquinavir may result in an increased concentration of saquinavir in the blood.

- Tacrolimus (used to prevent rejection of transplanted organs) - Taking PEPTISEC together with tacrolimus may result in an increased concentration of tacrolimus in the blood.
- Methotrexate (used to treat certain types of cancer or to control severe psoriasis or rheumatoid arthritis). In some patients, taking PEPTISEC together with methotrexate may increase the concentration of methotrexate in the blood. If you are taking a high dose of methotrexate, PEPTISEC may need to be temporarily withdrawn.
- Erlotinib (used to treat cancer) - Taking PEPTISEC together with erlotinib may reduce the effect of erlotinib. Concomitant use should therefore be avoided.
- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus). Taking PEPTISEC together with ketoconazole, itraconazole and posaconazole may result in a decreased effect of these medicines. Concomitant use with posaconzaole should be avoided.

  Taking PEPTISEC together with voriconazole may result in an increased concentration of PEPTISEC in the blood.
- Rifampicin (used to treat tuberculosis). Taking PEPTISEC together with rifampicin may result in a decreased effect of PEPTISEC.
- St John's wort (*Hypericum perforatum*) (used to treat mild depression). Taking PEPTISEC together with St John's wort may result in a decreased effect of PEPTISEC.

If you are using any of these medicines, you may not be able to take PEPTISEC, or you may need dosage adjustments or your doctor may need to monitor you carefully for side effects.

**PEPTISEC with food and drink**

Avoid alcohol while taking PEPTISEC as it may increase the side effects experienced.

**Pregnancy, breastfeeding and fertility**

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Do not take PEPTISEC capsules if you are pregnant or breastfeeding.

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 health care provider for advice before taking this medicine.

**Driving and using machines**

PEPTISEC may cause sleepiness/drowsiness and affect your ability to concentrate. These side effects may be worsened by taking PEPTISEC capsules together with alcohol or other central nervous system depressants (medicines used to slow down brain activity and that may make you sleepy; such as cold or allergy medicine, sleeping pills, muscle relaxers, and medicines for seizures, depression or anxiety). If you are affected, do not drive or use machinery.

It is not always possible to predict to what extent PEPTISEC may interfere with the daily activities of a patient. Patients should ensure that they do not engage in daily activities until they are aware of the measure to which PEPTISEC affects them.

**PEPTISEC contains sugar (mannitol and sucrose)**

PEPTISEC contains sucrose which is a sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking PEPTISEC.

PEPTISEC contains less than 23 mg sodium (salt) per capsule, that is to say essentially ‘sodium-free’.

**3. How to take PEPTISEC**

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

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

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It is recommended that you take PEPTISEC capsules in the morning.

Swallow PEPTISEC capsules whole with half a glass of liquid.

Do not chew or crush the capsules.

*Dosage:*

Your doctor will tell you how many capsules to take and how long to take them for.

If you have the impression that the effect of PEPTISEC is too strong or too weak, talk to your doctor or pharmacist.

**If you take more PEPTISEC than you should**

Blurred vision, confusion, excessive sweating, flushing (redness of skin), headache, general feeling of being unwell, nausea (queasiness, feeling that one is about to vomit), vomiting, dizziness, abdominal pain, diarrhoea and increased heart rate can occur.

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

**If you forget to take PEPTISEC**

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take PEPTISEC at the next regularly scheduled time. Do not take a double dose to make up for forgotten individual doses.

**If you stop taking PEPTISEC**

Do not stop taking PEPTISEC unless your doctor tells you to.

**4. Possible side effects**

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PEPTISEC can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to PEPTISEC. 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:

- Reddening of the skin with blisters or peeling. There may be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This may be associated with a high fever and joint pains. The skin rashes may develop into serious widespread skin damage (peeling of the top layer of the skin and mucous membranes) with life threatening consequences. This could be 'erythema multiforme', 'Subacute cutaneous lupus erythematosus', 'Stevens-Johnson syndrome', 'Toxic Epidermal Necrolysis', 'dermatitis acute generalised exanthematous pustulosis' or 'drug reaction with eosinophilia and systemic symptoms'.
- Blood problems such as a reduced number of white blood cells or platelets. This can cause weakness, bruising or make infections more likely.
- Inflammation of the liver (hepatitis), liver failure leading to brain damage, yellow skin, dark urine and tiredness which can be symptoms of liver problems.

- Symptoms such as severe (bloody or repeated watery) diarrhoea, with or without fever, abdominal pain or tenderness (you may have bowel inflammation caused by a bacterial infection).
- Kidney problems (interstitial nephritis) (you may notice a decrease in urine, blood in urine or experience water retention), which could lead to kidney failure.

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

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- Headache (If the headache is severe, it may be necessary to stop treatment with PEPTISEC)
- Effects on your stomach or gut: Diarrhoea (If the diarrhoea is severe, it may be necessary to stop treatment with PEPTISEC), constipation, abdominal pain or colic, wind (flatulence),
- Feeling sick (nausea) or being sick (vomiting).

*Less frequent side effects:*

- Enlarged breasts in men
- Low levels of sodium and magnesium in the blood. Symptoms include fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, or increased heart rate.
- Seeing, feeling or hearing things that are not there (hallucinations)
- Feeling agitated, confused or depressed
- Aggressiveness
- Trouble sleeping (insomnia)
- Dizziness
- Feeling sleepy
- Tingling feelings such as “pins and needles”

- Blurred vision
- Feeling of spinning (vertigo)
- Swelling of the ankles, feet or hands
- Suddenly feeling wheezy or short of breath (bronchospasm)
- Dry mouth
- An inflammation on the inside of the mouth
- Thrush in the gullet - white lesions in mouth, pain on swallowing, dry mouth may be experienced
- Taste changes
- Skin rash, itchy skin, lumpy rash (hives), skin sensitivity to light
- Hair loss
- Muscle or joint pain
- Fracture of the hip, wrist or spine, muscle weakness
- Lack of energy, generally feeling unwell
- Increased sweating

*Side effects of unknown frequency:*

- Extremely low levels of magnesium which can cause fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. 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.
- Inflammation of the colon (large intestine) that can cause watery diarrhoea and cramping.

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

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**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects to SAHPRA via the Adverse drug reaction and quality problem reporting form", found on SAHPRA's website: www.sahpra.org.za under "online services".

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

**5. How to store PEPTISEC**

- Store at or below 25 °C.
- Keep in the original package in order to protect from moisture.
- Keep the bottle tightly closed in order to protect from moisture.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the label or the carton.
- Return all unused tablets to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems.

**6. Contents of the pack and other information**

**What PEPTISEC contains**

The active substance is omeprazole.

PEPTISEC 10: Each capsule contains omeprazole 10 mg

PEPTISEC 20: Each capsule contains omeprazole 20 mg

PEPTISEC 40: Each capsule contains omeprazole 40 mg

The other ingredients are anhydrous disodium phosphate, hypromellose type 2910, macrogol 6000, magnesium hydroxide, mannitol, methacrylic acid-ethyl acrylate copolymer (1:1), polysorbate 80, purified water, sodium lauryl sulfate, sodium starch glycolate (type A), sugar spheres (containing sucrose and maize starch), talc, titanium dioxide.

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The PEPTISEC 10 capsule shell contains Brilliant blue FCF - FD&C Blue 1 (E133), gelatine, titanium dioxide (E171) and yellow iron oxide.

The PEPTISEC 20 capsule shell contains Indigotine-FD&C Blue 2 (E132), gelatine and titanium dioxide (E171).

The PEPTISEC 40 capsule shell contains black iron oxide, gelatine and titanium dioxide (E171).

**What PEPTISEC looks like and contents of the pack**

PEPTISEC 10: Hard gelatine capsule size “4”, with opaque green cap and opaque white body, containing white to off-white or white cream spherical regular pellets without detectable defects.

PEPTISEC 20: Hard gelatine capsule size “4”, with opaque blue cap and opaque white body, containing white to off-white of white cream spherical regular pellets without detectable defects.

PEPTISEC 40: Hard gelatine capsule size “3”, with opaque white cap and opaque grey body, containing white to off-white or white cream spherical regular pellets without detectable defects.

Transparent PVC-PE-PVDC/Aluminium blisters.

White HDPE bottles with silica gel desiccant contained in the cap.

Pack size: 7, 14, 28, 30, 56 or 100 hard gelatine gastro-resistant capsules.

Not all pack size may be marketed.

**APPROVED PATIENT INFORMATION LEAFLET FOR PEPTISEC**

**Holder of certificate of registration**

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