VENCID ENTERIC-COATED TABLET 40MG

Pantoprazole 40mg (as Pantoprazole Sodium Sesquihydrate)

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What is Vencid used for

It is used for the treatment of acid-related diseases of the stomach and intestine.

- Moderate to severe forms of gastrooesophageal reflux (oesophagus inflammation accompanied by the regurgitating of stomach acid).
- Duodenal and stomach ulcer.
- An infection with a bacterium called *Helicobacter pylori* in patients with duodenal ulcers and stomach ulcers in combination with two antibiotics (Eradication therapy).
- Zollinger-Ellison syndrome and other conditions producing too much acid in the stomach.

How Vencid works

Pantoprazole is a "selective proton pump inhibitor" something which reduces the amount of acid produced in your stomach.

Before you use Vencid

- When must not to use it

Do not take this medicine if you are:

- allergic (hypersensitivity) to the pantoprazole or any other ingredients in this medicine.
- taking atazanavir (a drug to treat HIV/AIDS).
- in combination treatment with antibiotics, and have moderate to severe liver or kidney problems.

- <u>Before you start use it</u>

Tell your doctor or pharmacist if you have:

- mild gastrointestinal complaints.
- unintentional weight loss.
- repeated vomiting.
- difficulty in swallowing.
- vomiting blood.
- anaemia.
- blood in stools
- severe liver problems.
- are pregnant or breast-feeding.

Moreover, tell your doctor before taking this medicine, if you are due to have a specific blood test (Chromogranin A).

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use Vencid

- How much to take

Gastro-oesophageal refluxinflammation of oesophagus:

20 to 40mg once daily in the morning for 4 weeks.

Duodenal ulcer:

40mg once daily in the morning for 2 weeks.

Gastric ulcer:

40mg once daily in the morning for 4 weeks.

Zollinger-Ellison syndrome: 80 mg daily.

Eradication of *Helicobacter pylori*: Triple therapy regimen (with two other antibiotics) taken in a week:

- i) 2 x 40mg Pantoprazole / day
- + 2 x 1g amoxicillin / day
- + 2 x 500mg clarithromycin / day
- ii) 2 x 40mg Pantoprazole / day
- + 2 x 400-500mg metronidazole / day
- + 2 x 250-500 mg clarithromycin / day
- ii) 2 x 40mg Pantoprazole / day
- + 2 x 1g amoxicillin / day
- + 2 x 500mg metronidazole / day

The second tablet should be taken before the evening meal.

Your doctor or pharmacist will prescribe based on individual conditions.

- When to use it

Once-daily doses should be taken one hour before breakfast.

If there is second dose in a day, it should be taken before the evening meal.

- How long to use it

Follow the prescription from your doctor or pharmacist.

Ask your doctor or pharmacist before prolong use of this medicine.

- If you forget to use it

Take it as soon as you remember, unless it is nearly time for your next dose, skip the missed dose. Then go on as before. Never double up on the next dose to make up for the one missed.

- <u>If you take too much (overdose)</u>

There are no known symptoms of overdose. In any case, doctor must be consulted.

While you are using it

- Things you must do

Always wash your hand before handle the tablets. Take the tablets with water and try to take at the same time each day.

- Things you must not do

Do not chew the tablets and swallow it with liquid.

Do not take this medicine by yourself without prescription from your doctor or pharmacist.

- Things to be careful of

Tell your doctor or pharmacist if you:

- are allergic to any of the ingredients in this medicine.
- have reduced levels of vitamin B12.
- have gastrointestinal infections.
- have weight loss, repeating vomiting, difficulty in swallowing.
- develop anaemia, vomiting blood, and stools with blood.
- are pregnant or breast-feeding.

Side effects

- Headache, diarrhoea, and skin rashes.
- Dizziness, fatigue, constipation, nausea and vomiting, stomach bloating, abdominal pain, joint and muscle pain, itchy skin with hives, and dry mouth.

Seek immediate medical attention if you experience any side effects or allergic reactions.

When you are taking this medicine, your doctor will want to monitor you (especially if you are taking it for long term). Hence, you should report any new and exceptional symptoms and circumstances whenever you see your doctor. Please tell your doctor promptly if you get any of the symptoms below:

- Rash (especially in areas exposed to the sun), possibly with pain in the joints. (Subacute Cutaneous Lupus Erythematosus, SCLE)
- Fever, extreme tiredness, pus/blood in urine.
- Involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate
- Fracture in the hip, wrist or spine
- Watery stool, stomach pain and fever that do not go away

- Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems (depression, memory loss or behavioral changes).
 - a) Subacute Cutaneous Lupus
 Erythematosus (SCLE)
 Frequency "not known"
 - b) <u>Interstitial Nephritis</u> Kidney problems (Interstitial nephritis)
 - Frequency "not known": Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood.
 - d) Fracture
 Frequency "uncommon": Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).
 - e) <u>Clostridium Difficile Diarrhea</u> Severe diarrhea which may be caused by an infection (Clostridium difficile) in your intestines.
- f) Fundic Gland Polyps (Benign)
 Frequency "common": Benign
 polyps in the stonmach
- g) <u>Vitamin B12 Deficiency</u> Proton pump inhibitors may cause vitamin B12 deficiency.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my [Public → Reporting Side Effects to Medicinal (ConSERF) or Vaccine (AEFI)].

Storage and Disposal of Vencid

- <u>Storage</u>

Store at room temperature below 30 °C. Keep out of the reach of the children. Do not use this medicine after expiry date.

- <u>Disposal</u>

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Beige, round, normal convex enteric coated tablet, in blister strips of 7's in packing of 14 tablets per box.

- Ingredients

- Active ingredient(s)
 Pantoprazole 40 mg
 (as Pantoprazole Sodium Sesquihydrate).
- Inactive ingredients
 Crospovidone, Mannitol, Povidone,
 Sodium Carbonate
 Anhydrous, Magnesium Stearate,
 Hydroxypropyl Methylcellulose
 Compound
 Mix, Methacrylic Acid Copolymer
 Compound Mix, Purified Water.
- MAL number(s): MAL12115066AZ

Manufacturer and Product Registration Holder

Xepa-Soul Pattinson (Malaysia) Sdn Bhd 1-5 Cheng Industrial Estate, 75250 Melaka, Malaysia.

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