

Pantoprazole BEXIMCO 20mg/40mg Gastro-Resistant Tablet

Pantoprazole Sodium USP equivalent to Pantoprazole 20mg/40mg

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Please read this leaflet carefully before you start using Pantoprazole Tablet. It will advise you how it should be taken properly and when to tell your doctor about health-related conditions. If you have any questions or need more advice, ask your doctor, professional healthcare provider or pharmacist.

What Pantoprazole Tablet is used for
Pantoprazole BEXIMCO Gastro-Resistant Tablet is a selective “proton pump inhibitors”, which is used for treating acid-related disease of the stomach and intestine.

Pantoprazole BEXIMCO 20 mg Gastro-Resistant Tablet

Treatment of mild reflux disease and associated symptoms (eg, heartburn, acid regurgitation, pain on swallowing); long-term management and prevention of relapse in reflux esophagitis; prevention of stomach and intestinal ulcers induced by nonsteroidal anti-inflammatory drugs (NSAIDs), in patients at risk with a need for a continuous NSAID treatment.

Pantoprazole BEXIMCO 40 mg Gastro-Resistant Tablet

In combination with 2 appropriate antibiotics for the eradication of *Helicobacter pylori* in patients with stomach ulcers to reduce recurrence of intestine and stomach ulcers caused by the microorganism; intestine and stomach ulcers.

Also 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.

Zollinger-Ellison syndrome: A rare disorder caused by a tumor called a gastrinoma, most often occurring in the pancreas. The tumor secretes the hormone gastrin, which causes increased production of gastric acid leading to severe recurrent ulcers of the esophagus, stomach, and the upper portions of the small intestine (the duodenum and jejunum).

Gastrinomas resulting in the Zollinger-Ellison's syndrome are not limited to the pancreas but may also occur in the stomach, duodenum, spleen and lymph nodes.

And other diseases which cause the body to produce excess stomach acid.

How Pantoprazole Tablet works

They exert their action by reducing the amount of the acid production in your stomach.

Before you use Pantoprazole Tablet

Do not use Pantoprazole if you have any of the following conditions listed below. If any of these apply to you, tell your doctor before starting to use Pantoprazole.

- When you must not use it

- If you are sensitive to Pantoprazole or to any of the other excipients of the Pantoprazole BEXIMCO Gastro-Resistant Tablet.
- If you are allergic to medicines containing other proton pump inhibitors eg. Omeprazole, lansoprazole etc.
- For the combination treatment of *Helicobacter pylori* if you have kidney or liver disorders.
- If you are taking atazanavir.

- Before you start to use it

Please tell your doctor or pharmacist your medical history, especially if:

- you need to take NSAIDs therapy, because you have an increased risk of developing stomach and intestinal complications. Any increased risk will be assessed according to your own personal risk factors such as your age (65 years old or more), a history of stomach or duodenal ulcers or of stomach or intestinal bleeding.
- if you have severe liver problem. If you have ever had problems with your liver, should consult your doctor to check your liver enzyme

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

- Taking other medicines

Pantoprazole BEXIMCO Gastro-Resistant Tablet may influence the effectiveness of other medicines, please tell your doctor if you are taking:

- Medicines eg. ketoconazole (used to treat fungal infections) and atazanavir. Pantoprazole may reduce the effectiveness of these and other medicines.
- Coumarin anticoagulants eg. Phenprocoumon and warfarin. Blood checkups may be needed if taken with Pantoprazole.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicine obtained without a prescription.

How to use Pantoprazole Tablet

How much to use

When to use it

How long to use it

Unless told otherwise by your doctor, the usual dose is:

Pantoprazole BEXIMCO 20 mg Gastro-Resistant Tablet

Adults and adolescents 12 years of age and above :

To treat mild reflux disease and associated symptoms (i.e heartburn, acid regurgitation, pain on swallowing)

The usual dose is 20mg a day but the dosing depends on the severity of the disease. Your doctor will tell you how long to take your medicine. 20mg a day, dose usually brings relief within 2-4 weeks. The mild inflammation of the oesophagus will need 4 weeks to heal. After this any reoccurring symptoms can be controlled by taking 20mg daily, as required.

For long-term management and for preventing the return of reflux oesophagitis

20mg a day. The dose may be increased to 40mg once a day if the illness returns. After healing, you can reduce the dose back again to 20 mg a day.

Adults: 20mg a day is recommended for preventing duodenal and stomach ulcer in patient who need to take NSAIDs continuously.

Pantoprazole BEXIMCO 40 mg Gastro-Resistant Tablet

Adults and adolescent 12 years of age and above: To treat severe reflux oesophagitis and its symptoms The usual dose is 40mg a day. Your doctor will tell you how long to take your medicine.

Adults: For the treatment of an infection with a bacterium called *Helicobacter pylori* in patients with duodenal ulcers and stomach ulcers in combination with two antibiotics (Eradication therapy) 40mg, two times a day plus two antibiotic tablets of either amoxicillin, clarithromycin or metronidazole, each to be taken two times a day with your pantoprazole tablet. Take the first pantoprazole tablet 1 hour before breakfast and the second pantoprazole tablet 1 hour before your evening meal. Follow your doctor's instructions and make sure you read the package leaflets for these antibiotics.

For the treatment of stomach and duodenal ulcers The usual dose is 40mg a day. After consultation with your doctor, the dose may be doubled. Your doctor will tell you how long to take your medicine.

For the long-term treatment of Zollinger-Ellison-Syndrome and of other conditions in which too much stomach acid is produced The recommended starting dose is usually 80mg a day. Take the two tablets 1 hour before a meal. Your doctor may later adjust the dose,

depending on the amount of stomach acid you produce. If prescribed more than 80mg a day, the tablets should be taken twice daily. If your doctor prescribes a daily dose of more than 160mg a day, you will be told exactly when to stop taking the medicine.

- If you forget to use it

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

- If you use too much (overdose)

If overdose is suspected, contact your local poison control centre or emergency room immediately.

While you are using it

- Things you must do

Take Pantoprazole tablets as directed by your doctor. You should check with your doctor or pharmacist if you are not sure.

Take the tablets 1 hour before a meal without chewing and breaking and swallow them whole with some water.

- Things you must not do

- Pregnancy and breastfeeding: There are no adequate data from the use of Pantoprazole in pregnant women. It is not known whether Pantoprazole is excreted in human breast milk. If you are pregnant or think you may be pregnant or if you are breast feeding, you should use this medicine only if your doctor considers the benefits for you greater than the risks. Ask your doctor or pharmacist for advice before taking any other medicine.
- Do not share this medication with others.

- Things to be careful of

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

- An unintentional loss of weight
- Recurrent vomiting
- Difficulties in swallowing
- Blood in vomiting

- You look pale and feel weak (anaemia)
- You notice bloody stools
- Severe and / or persistent diarrhea as Pantoprazole BEXIMCO Gastro-Resistant Tablet have been associated with a small increase in infectious diarrhea

Pantoprazole may alleviate the symptoms of cancer and could cause delay in their diagnosis. Your doctor may decide that you need some tests to rule out malignant disease. If your symptoms continue in spite of your treatment, further investigations will be considered. If you are on long-term Pantoprazole treatment your doctor will probably keep you under regular surveillance. If you notice any other side effect other than listed in this leaflet, please contact your doctor.

Side effects

Like all medicines, Pantoprazole can have side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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) Interstitial Nephritis

Kidney problems (interstitial nephritis)

c) Hypomagnesaemia

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) Clostridium Difficile Diarrhea

Severe diarrhoea which may be caused by an infection (Clostridium difficile) in your intestines.

f) Fundic Gland Polyps (Benign)

Frequency "Common": Benign polyps in the stomach

g) Vitamin B12 Deficiency

Proton pump inhibitors may cause vitamin B12 deficiency.

Frequency 'not known': Inflammation in the large bowel, that causes persistent watery diarrhea

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Pantoprazole Tablet

- Storage

Store at room temperature below 30°C. Keep in a dry place, protected from light and out of the reach of children.

- Disposal

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

Product Description

- What it looks like

Pantoprazole BEXIMCO Gastro-Resistant tablet are yellow colored, oval, biconvex, enteric coated tablets plain on both sides.

Pantoprazole BEXIMCO 20 mg

Gastro-Resistant Tablet:

Length: 9.0mm ± 2mm

Width: 4.8mm ± 2mm

Pantoprazole BEXIMCO 40 mg

Gastro-Resistant Tablet:

Length: 11.9mm ± 2mm

Width: 6.0mm ± 2mm

- Ingredients

- Active ingredient
Pantoprazole Sodium Sesquihydrate

- Inactive ingredients
Mannitol, Sodium Carbonate Anhydrous, Crospovidone, Povidone K-30, Calcium Stearate, Purified water, Hydroxypropylmethyl Cellulose, Polyethylene Glycol-6000, Purified talc, Methacrylic Acid-ethyl Acrylate Copolymer Dispersion, Triethyl citrate, Opadry AMB 80W52172, Carnauba Wax (Powder)

- MAL number:

MAL15065043AZ

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Manufacturer

Beximco Pharmaceuticals Ltd.
126, Kathaldia, Auchpara, Tongi,
Gazipur, Bangladesh

Product Registration Holder

Vitamode Sdn. Bhd.,
55, Lorong Sempadan 2,
11400 Ayer Itam,
Penang, Malaysia

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