Pantoprazole 20 mg gastro-resistant tablets

Uses

Pantoprazole is indicated for use in adults and adolescents 12 years of age and above for:

• Symptomatic gastro-oesophageal reflux disease.

• long-term management and prevention of relapse in reflux oesophagitis.

For long-term management and prevention of relapse in reflux oesophagitis.

Pantoprazole is indicated for use in adults for: Prevention of gastroduodenal ulcers induced by non-selective non-steroidal anti-inflammatory drugs (NSAIDs) in patients at risk with a need for continuous NSAID treatment.

Dose and method of administration

Adults and adolescents 12 years of age and above: Symptomatic gastro-oesophageal reflux disease: The recommended oral dose is one gastro-resistant tablet Pantoprazole 20 mg per day. Symptom relief is generally accomplished within 2-4 weeks. If this is not sufficient, symptom relief will normally be achieved within a further 4 weeks. When symptom relief has been achieved, reoccurring symptoms can be controlled using an on-demand regimen of 20 mg once daily, taking one tablet when required. A switch to continuous therapy may be considered in case satisfactory symptom control cannot be maintained with on-demand treatment.

Long-term management and prevention of relapse in reflux oesophagitis: For long-term management, a maintenance dose of one gastro-resistant tablet Pantoprazole 20 mg per day is recommended, increasing to 40 mg pantoprazole per day if a relapse occurs. Pantoprazole 40 mg is available for this case. After healing of the relapse the dose can be reduced again to 20 mg pantoprazole.

Adults: Prevention of gastroduodenal ulcers induced by non-selective non-steroidal anti-inflammatory drugs (NSAIDs) in patients at risk with a need for continuous NSAID treatment. The recommended oral dose is one gastro-resistant tablet Pantoprazole 20 mg per day.

Special populations: Patients with hepatic Impairment: A daily dose of 20 mg pantoprazole should not be exceeded in patients with severe liver impairment.

Patients with renal Impairment: No dose adjustment is necessary in patients with impaired renal function.

Elderly: No dose adjustment is necessary in the elderly .

Paediatric population: Pantoprazole is not recommended for use in children below 12 years of age due to limited data on safety and efficacy in this age group.

Method of administration: Oral use: The tablets should not be chewed or crushed and should be swallowed whole 1 hour before a meal with some water.

Contraindications

- Hypersensitivity to the active substance, substituted benzimidazoles or to any of the excipients listed:
- Tablet core: Sodium Carbonate, Mannitol, Crospovidone (Type B), Hydroxypropyl Cellulose, Calcium Stearate
- Coating: Hypromellose, Yellow iron oxide (E172), Methacrylic Acid-Ethyl Acrylate copolymer (1:1) dispersion 30%, Sodium laurilsulfate , Polysorbate 80, Triethyl Citrate
- Printing ink: Shellac, Red Iron Oxide (E172),Black Iron Oxide (E172),Yellow Iron oxide (E172),Propylene Glycol, Ammonia solution, concentrated

Interactions

Medicinal products with pH-Dependent Absorption Pharmacokinetics: Because of profound and long lasting inhibition of gastric acid secretion, pantoprazole may interfere with the absorption of medicinal products where gastric is an important determinant of oral bioavailability e.g. some azole antifungals such as ketoconazole, itraconazole, posaconazole and other medicines such as erlotinib.

HIV protease inhibitors: Co-administration of pantoprazole is not recommended with HIV protease inhibitors for which absorption is dependent on acidic intragastric pH such as atazanavir due to significant reduction in their bioavailability. If the combination of HIV protease inhibitors with a proton pump inhibitor is judged unavoidable, close clinical monitoring (e.g. virus load) is recommended. A pantoprazole dose of 20 mg per day should not be exceeded. Dosage of the HIV protease inhibitor may need to be adjusted

Coumarin anticoagulants (phenprocoumon or warfarin): Co-administration of pantoprazole with warfarin or phenprocoumon did not affect the pharmacokinetics of warfarin, phenprocoumon or INR. However, there have been reports of increased INR and prothrombin time in patients receiving PPIs and warfarin or phenprocoumon concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding, and even death. Patients treated with pantoprazole and warfarin or phenprocoumon may need to be monitored for increase in INR and prothrombin time.

Methotrexate: Concomitant use of high dose methotrexate (e.g. 300 mg) and proton-pump inhibitors has been reported to increase methotrexate levels in some patients. Therefore, in settings where high-dose methotrexate is used, for example cancer and psoriasis, a temporary withdrawal of pantoprazole may need to be considered.

Undesirable effects

Frequency System Organ Class	Common	Uncommon	Rare	Very rare	Not known
Blood and lymphatic system disorders			Agranulocytosis	Thrombocytopenia; Leukopenia; Pancytopenia	
Immune system disorders			Hypersensitivity (including anaphylactic reactions and anaphylactic shock)		
Metabolism and nutrition disorders			Hyperlipidaemias and lipid increases (triglycerides, cholesterol); Weight changes		Hypomagnesaemia. (See section 4.4); Hypocalcaemia(1) Hypokalaemia(1)
Psychiatric disorders		Sleep disorders	Depression (and all aggravations)	Disorientation (and all aggravations)	Hallucination; Confusion (especially in pre-disposed patients, as well as the aggravation of these symptoms in case of pre-existence)
Nervous system disorders		Headache; Dizziness	Taste disorders		Paraesthesia
Eye disorders			Disturbances in vision / blurred vision		
Gastrointestinal disorders	Fundic gland polyps (benign)	Diarrhoea; Nausea / vomiting; Abdominal distension and bloating; Constipation; Dry mouth; Abdominal pain and discomfort			Microscopic colitis
Hepatobiliary disorders		Liver enzymes increased (transaminases, γ-GT)	Bilirubin increased		Hepatocellular injury; Jaundice; Hepatocellular failure
Skin and sub-cutaneous tissue disorders		Rash / exanthema / eruption; Pruritus	Urticaria; Angioedema		Stevens-Johnson syndrome; Lyell syndrome; Erythema multiforme; Photosensitivity, Subacute cutaneous lupus erythematosus (see section 4.4). Drug reaction with eosinophilia and systemic symptoms (DRESS)
Musculoskeletal and connective tissue disorders		Fracture of the hip, wrist or spine (see section 4.4)	Arthralgia; Myalgia		Muscle spasm(2)
Renal and urinary disorders					Nephritis (with possible progression to renal failure)
Reproductive system and breast disorders			Gynaecomastia		
General disorders and administration site conditions		Asthenia, fatigue and malaise	Body temperature increased; Oedema peripheral		

Pregnancy and lactation

Pregnancy: A moderate amount of data on pregnant women (between 300-1000 pregnancy outcomes) indicate no malformative or feto/ neonatal toxicity of Pantoprazole. As a precautionary measure, it is preferable to avoid the use of Pantoprazole during pregnancy.

Breast-feeding: Animal studies have shown excretion of pantoprazole in breast milk. There is insufficient information on the excretion of pantoprazole in human milk but excretion into human milk has been reported. A risk to the newborns/infants cannot be excluded. Therefore, a decision on whether to discontinue breast-feeding or to discontinue/abstain from Pantoprazole therapy taking into account the benefit of breast-feeding for the child, and the benefit of Pantoprazole therapy for the women.

How to store

This medicinal product does not require any special storage conditions