Pantid®

Pantoprazole

Description: Pantoprazole is a proton pump inhibitor(PPI) used for the treatment of acid-pepsin diseases. Like other drugs in this class, pantoprazole causes long-time inhibition of acid secretion by inactivating the parietal cell H^+-K^+ ATPase.

Pharmacokinetics: Pantoprazole peak serum concentration(C_{max}) and area under the serum concentration-time curve (AUC) increase in a manner proportional to doses. Pantoprazole does not accumulate and its pharmacokinetics are unrelated with multiple daily dosing. Pantoprazole is extensively metabolized in the liver through cytochrome P450 (CYP) system. Pantoprazole metabolism is independent of the route of administration(Intravenous or oral). The main metabolic pathway is demethylation by CYP2C19, with subsequent sulfation; other metabolic pathways include oxidation by CYP3A4. Administration of oral dose of pantoprazole with food may delay its absorption up to 2 hours or longer; however, the C_{max} and the extent of pantoprazole absorption (AUC) are not altered. After administration of a single intravenous dose of pantoprazole to healthy, normal subjects, approximately 71% of the dose is excreted in the urine with 18% excreted in the feces through biliary excretion.

Composition: Pantid® 20 mg Tablet: Each enteric-coated tablet contains Pantoprazole Sodium Sesquihydrate USP 22.5 mg equivalent to Pantoprazole 20 mg.
Pantid® 40 mg Tablet: Each enteric-coated tablet contains Pantoprazole Sodium Sesquihydrate USP 45.1 mg equivalent to Pantoprazole 40 mg.
Pantid® 40 Injection: Each vial contains Pantoprazole Sodium Sesquihydrate Sterile Lyophilized Powder 32% USP 125 mg equivalent to Pantoprazole 40 mg.

Indication and Dosage

Tablet

Indication	Dosage
Benign gastric and duodenal ulcer	Pantoprazole 40 mg once daily for 4-8 weeks for gastric ulcer and 2-4 weeks for duodenal ulcer.
GERD	Pantoprazole 20-40 mg once daily for 4-8 weeks.
Eradication of Helicobacter pylori (in combination with antibiotics)	Triple therapy of pantoprazole 40 mg twice daily in combination with appropriate antibiotics for 1-2 weeks.
Prophylaxis of NSAID associated ulcer	Pantoprazole 20 mg daily.
Zollinger-Ellison syndrome	Initially 80 mg once daily adjusted according to response (Elderly Max. 40 mg daily); daily doses above 80 mg given in 2 divided doses.
Peptic ulcer bleeding	40 mg IV bolus then 6.7mg/h continuous infusion X 72 h (160 mg/d after bolus).
Bleeding or severe erosive esophagitis	40 mg IV once daily for 7 to 10 days.
Pathologic hypersecretion/ Zollinger-Ellision syndrome	80 mg IV every 12 hours; may increase to 80 mg every 8 hours if needed; may titrate to higher doses depending on acid output.
Stress ulcer prophylaxis	80 mg IV every 12 h for 24 h followed by 40 mg every 12 h.

Reconstitution and method of administration:

For two minutes infusion
Pantid® IV for injection should be reconstituted with 10 ml of 0.9% NaCl injection and administered intravenously over a period of approximately 2 minutes.

For fifteen minutes infusion
Reconstituted **Pantid®** IV for injection should be further diluted (admixed) with 100 ml of 5% Dextrose Injection, 0.9% NaCl Injection or Lactated Ringer's Injection. The reconstituted solution may be stored for up to 2 hours at room temperatures prior to further dilution; the admixed solution may be stored up to 12 hours at room temperature prior to intravenous infusion. Neither the reconstituted solution nor the admixed solution need to be protected from light.

Contraindications: Pantid® should not be used in cases of known hypersensitivity to pantoprazole.

Side effects: There have been rare reports of other gastrointestinal complaints such as upper abdominal pain, constipation or flatulence and allergic reactions such as skin rash and pruritus(in isolated cases also urticaria, angioedema or anaphylactic reactions including anaphylactic shock). Occasionally, there have been reports of nausea, vomiting, dizziness and disturbances in vision (blurred vision). Peripheral oedema, fever, thrombophlebitis, depression or myalgia-subsiding after termination of therapy-have been reported in individual cases.

Use in pregnancy and lactation: Pregnancy category B. However, Prantoprazole should not be used during pregnancy and lactation unless the benefit exceeds the potential risk.

Special warnings and precautions: Pantoprazole should be used with caution in patients with liver disease, in pregnancy and breast-feeding. Symptomatic response to therapy with pantoprazole does not preclude the presence of gastric malignancy.

Pantoprazole injection is for intravenous administration **ONLY** and must **NOT** be given by any other route.

Drug interactions: No clinically significant interactions were observed in specific tests with a number of such drugs or compounds, namely antipyrine, caffeine, carbamazepine, diazepam, diclofenac, digoxin, ethanol, glibenclamide, metoprolol, naproxen, nifedipine, phenytoin, piroxicam, theophylline and an oral contraceptive. There were also no interactions with concomitantly administered antacids.The response to anticoagulants such as warfarin, phenprocoumon or acenocoumarol may be affected by any concomitant medication.

Storage: Keep out of reach of children. Store in a dry place, below 25˚C temperature and protected from light.

Packaging
Pantid® 20 mg Tablet: Each carton contains 14X7 tablets in alu-alu blister.
Pantid® 40 mg Tablet: Each carton contains 14X4 tablets in alu-alu blister.
Pantid® 40 Injection: Each carton contains 1 vial of 40 mg pantoprazole, 1 ampoule contains 10 ml of sterile 0.9% sodium chloride injection and 10 ml disposable syringe.

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Opsonin Pharma
Ideas for healthcare

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