Xeldrin®

Omeprazole

Description

Xeldrin® is a preparation of Omeprazole, which is a proton pump inhibitor, weak base in nature and is concentrated and converted to the active form in the highly acidic environment of the intracellular canaliculi within the parietal cell, where it inhibits the enzyme H^+/K^+- ATPase, the acid pump. This effect on the final step of the gastric acid formation process is dose-dependent and provides for highly effective inhibition of both basal acid secretion and stimulated acid secretion, irrespective of the stimulus.

Indications

Xeldrin® Capsule is indicated in:

- Reflux Esophagitis
- Gastroesophageal Reflux Disease
- Duodenal Ulcer
- Benign Gastric Ulcer
- Refractory Peptic Ulcer
- Treatment of ulcer induced by NSAIDs
- Acid-related Dyspepsia
- Eradication of *Helicobacter pylori* (In combination with antibiotics)
- Zollinger-Ellison Syndrome
- Erosive Esophagitis (EE) due to Acid-Mediated GERD

Xeldrin® 40 IV Injection is indicated in:

- Prophylaxis of acid aspiration
- Reflux Esophagitis
- Duodenal Ulcer
- Benign Gastric Ulcer
- Zollinger-Ellison Syndrome

Dosage and administration

Xeldrin® Capsule

Duodenal Ulcer: The adult dose for duodenal ulcer is 20 mg **Xeldrin®** once daily for 4 weeks. Some patients may require an additional 4 weeks of therapy.

Benign Gastric Ulcer: The usual dose is 20 mg **Xeldrin®** once daily for 8 weeks. In severe cases, the dose may be increased to 40 mg once daily.

Reflux esophagitis and Gastroesophageal Reflux Disease: The adult dose for severe erosive esophagitis or poorly responsive gastroesophageal reflux disease is 20 mg **Xeldrin®** for 4 to 8 weeks. Children (over 1 to 16 years): 5 mg once daily (5 to less than 10 kg body weight), 10 mg once daily (10 to less than 20 kg body weight), 20 mg once daily (20 kg and greater body weight) for 4 to 8 weeks.

Ulcer induced by NSAID: The recommended dose of 20 mg **Xeldrin®** once daily for 4 to 8 weeks.

Acid Reflux Disease: For long-term management **Xeldrin®** 10 mg once daily, increasing to 20 mg if symptoms return.

Acid-related Dyspepsia: The usual dosage is **Xeldrin®** 10 mg or 20 mg once daily for 2-4 weeks depending on the severity and persistence of symptoms.

Eradication of Helicobacter pylori: Triple therapy/dual therapy regimen of **Xeldrin®** 20 mg/40 mg in combination with appropriate antibiotic can be used.

Zollinger-Ellison Syndrome: 60 mg **Xeldrin®** once daily. Dose may be increased to 120 mg daily depending on the severity. Daily dosage of greater than 80 mg should be administered in divided doses.

Erosive Esophagitis (EE) due to Acid-Mediated GERD:

Adult: The adult dose for Erosive Esophagitis (EE) due to Acid-Mediated GERD is 20 mg **Xeldrin®** once daily for 4 to 8 weeks.
Children:
Over 1 to 16 years: 5 mg once daily (5 to less than 10 kg body weight), 10 mg once daily (10 to less than 20 kg body weight), 20 mg once daily (20 kg and greater body weight) for 4 to 8 weeks.
1 month to less than 1 year: 2.5 mg once daily (3 to less than 5 kg body weight), 5 mg once daily (5 to less than 10 kg body weight), 10 mg once daily (10 kg and greater body weight) for up to 6 weeks.
Neonate (1 to 28 days): 0.7 mg/kg body weight once daily for 7-14 days then increased if necessary to 1.4-2.8 mg/kg once daily.

***Note:* The Xeldrin® capsule may be opened and pellets to be mixed immediately with a glass of cool water to ensure complete swallowing of the pellets. Do not chew or crash the pellets.**

Xeldrin® IV Injection

Prophylaxis of Acid Aspiration: **Xeldrin®** 40 mg IV injection to be given slowly, one hour before surgery.

Duodenal Ulcer, Gastric Ulcer, Reflux Esophagitis: **Xeldrin®** 40 mg IV injection once daily.

Zollinger-Ellison Syndrome: Initial dose is 60 mg once daily. Higher daily doses may be required and the dose should be adjusted individually. When dose exceed 60 mg daily, the dose should be divided and given twice daily.

Children: There is limited experience with Omeprazole for intravenous use in children.
Elderly: Dosage adjustment is not necessary.

Patients with impaired hepatic function
As bioavailability and plasma half-life is increased in patients with impaired hepatic function, the dose requires adjustment and a daily dose of 10 to 20 mg may be sufficient.

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

Method of administration for injection
Xeldrin® 40 mg IV injection should be given as a slow intravenous injection. Reconstitute the contents in vial with 10 ml supplied water for injection BP (No other solvent should be used). Discoloration may occur if incorrect reconstitution technique is used. After reconstitution the injection should be given slowly over a period of at least 2.5 minutes at a maximum rate of 4 ml per minute. Use only freshly prepared solution. Reconstituted solution is stable for up to 4 hours at 25°C.

Infusion
For IV infusion, dissolve the content of one vial of **Xeldrin**® 40 mg IV injection with 100 ml 0.9% Sodium Chloride solution or 5% Dextrose solution to make a solution of 0.4 mg/ml of Omeprazole approximately. The resultant infusion should be given intravenously over a period of 20-30 minutes or more. The solution should be used within 12 hours when Omeprazole is dissolved in 0.9% Sodium Chloride and within 6 hours when dissolved in 5% Dextrose. After reconstitution, start the infusion immediately. The constituted solution should not be mixed or co-administered in the same infusion set with any other drug.

Use in pregnancy & lactation
Pregnancy: Not known to be harmful.
Lactation (Breastfeeding): Present in milk but not known to be harmful.

Precautions
Omeprazole may alleviate symptoms and delay diagnosis of gastric carcinoma.

Side effects
Omeprazole is generally well tolerated. In rare occasion nausea, headache, diarrhea, constipation and flatulence have been reported. Skin rashes have been reported in a few patients. These adverse events have usually been mild and transient and there has been no consistent relationship with treatment.

Contraindications
There is no known contraindication to the use of Omeprazole.

Overdoses
There is no information available on the effects of overdoses in human. Animal toxicology: In life-long studies in rats, gastric ECL-cell hyperplasia and carcinoid, localized to the oxyntic mucosa, have been observed. These changes have been related to sustained hypergastrinaemia. No treatment related mucosal changes have been observed in patients treated continuously for periods up to 4 years.

Drug interactions
Omeprazole can prolong the elimination of diazepam, warfarin and phenytoin drugs that are metabolized by oxidation in the liver. Monitoring and dose adjustment is recommended for the patients receiving warfarin and phenytoin in addition to Omeprazole. There is no evidence of an interaction of Omeprazole with theophylline, propranolol and antacids.

Pharmaceutical precautions
Store in a cool (below 25°C) & dry place. Protect from light & moisture. Keep away from the reach of children.

Presentation
Xeldrin® 10 mg Capsule: Each capsule contains Omeprazole BP 10 mg as enteric coated pellets.
Xeldrin® 20 mg Capsule: Each capsule contains Omeprazole BP 20 mg as enteric coated pellets.
Xeldrin® 40 mg Capsule: Each capsule contains Omeprazole BP 40 mg as enteric coated pellets.
Xeldrin® 40 mg IV Injection: Each vial contains Omeprazole 40 mg as Sodium BP.

Package quantities
Xeldrin® 10 mg Capsule: Carton of 50 capsules in blister.
Xeldrin® 20 mg Capsule: Carton of 100 capsules and 80 capsules (for export) in blister.
Xeldrin® 40 mg Capsule: Carton of 40 capsules in blister.
Xeldrin® 40 mg IV Injection: Carton containing 1 vial of 40 mg Omeprazole, 1 ampoule of 10 ml water for injection BP and 1 disposable syringe (10 ml).

Xeldrin® 40 mg IV Injection manufactured by Popular Pharmaceuticals Ltd. (Only API Part) for Advanced Chemical Industries Limited.

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