Palo**tic**

Palonosetron

Palo**tic** 0.5 Tablet: Each tablet contains Palonosetron Hydrochloride USP equivalent to 0.5 mg Palonosetron.

Palo**tic** 0.25 Injection: Each ampoule contains Palonosetron Hydrochloride USP equivalent to 0.25 mg Palonosetron.

Palo**tic** 0.075 Injection: Each ampoule contains Palonosetron Hydrochloride USP equivalent to 0.075 mg Palonosetron.

Description

Palonosetron Hydrochloride is an antiemetic and antinauseant agent. It is a serotonin subtype 3 (5-HT_3) receptor antagonist with a strong binding affinity for this receptor. The empirical formula is $C_{19}H_{24}N_2O.HCl$, with a molecular weight of 332.87. Palonosetron Hydrochloride exists as a single isomer. Palonosetron Hydrochloride is a white to off-white crystalline powder. It is freely soluble in water, soluble in propylene glycol, and slightly soluble in ethanol and 2-propanol.

Mechanism of Action

Palonosetron is a 5-HT_3 receptor antagonist with a strong binding affinity for this receptor and little or no affinity for other receptors. It is thought that chemotherapeutic agents produce nausea and vomiting by releasing serotonin from the enterochromaffin cells of the small intestine and that the released serotonin then activates 5-HT_3 receptors that are located on the nerve terminals of the vagus in the periphery and centrally in the chemoreceptor trigger zone of the area postrema, to initiate the vomiting reflex. Postoperative nausea and vomiting is influenced by multiple patient, surgical and anesthesia related factors and is triggered by release of 5-HT_3 in a cascade of neuronal event involving both the central nervous system and the gastrointestinal tract. The 5-HT_3 receptor has been demonstrated to selectively participate in the emetic response. Palonosetron works by blocking the actions of serotonin, associated with nausea and vomiting, at 5-HT_3 receptor. It is likely that Palonosetron works in the small intestine but it may also work in the brain.

Indications

Palonosetron is a serotonin subtype 3 (5-HT_3) receptor antagonist indicated for:

• Moderately emetogenic cancer chemotherapy - prevention of acute and delayed nausea and vomiting associated with initial and repeat courses.

• Highly emetogenic cancer chemotherapy - prevention of acute nausea and vomiting associated with initial and repeat courses.

• Prevention of postoperative nausea and vomiting (PONV) for up to 24 hours following surgery. Efficacy beyond 24 hours has not been demonstrated.

Palonosetron is indicated in pediatric patients aged 1 month to less than 17 years for:

• Prevention of acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including highly emetogenic cancer chemotherapy.

Dosage and Administration

Usual dosage: Adult tablet dosage: 0.5 mg (01 tablet) daily. Adult IV dosage: A single IV dose of 0.075 mg should be administered over 10 seconds.

Chemotherapy-induced nausea and vomiting: Adult tablet dosage: 0.5 mg (01 tablet) administered approximately 1 hour prior to the start of chemotherapy. Adult IV dosage: A single IV dose of 0.25 mg should be administered over 30 seconds approximately 30 minutes before the start of chemotherapy.

Radiotherapy-induced nausea and vomiting: A single IV dose of 0.25 mg should be administered over 30 seconds approximately 30 minutes before each week of radiation fraction.

Post-operative nausea and vomiting: A single IV dose of 0.075 mg should be administered over 10 seconds immediately before induction of anesthesia.

Children dosage: (1 month to 17 years): A single IV dose at 20 mcg/kg body weight. Which maximum dose is 1.5 mg.

Contraindications

Contra-indicated in patients known to have hypersensitivity to the drug or any of its components.

Warnings and Precautions

Hypersensitivity reactions, including anaphylaxis, have been reported with or without known hypersensitivity to other selective 5-HT_3 receptor antagonists.

Adverse Reactions

The most common adverse reactions in chemotherapy-induced nausea and vomiting (incidence 5%) are headache and constipation. The most common adverse reactions in postoperative nausea and vomiting (incidence 2%) are QT prolongation, bradycardia, headache and constipation.

Drug Interactions

The potential for clinically significant drug interactions with Palonosetron appears to be low.

Use in Specific Populations

Use in pregnancy and lactation: Pregnancy category 'B'. It is not known whether Palonosetron is excreted in breast milk.

Use in elderly patients: No dosage adjustment is recommended in elderly patient ≥ 65 years of age.

Use in children (1 month to 17 years): A single IV dose at 20 mcg/kg body weight which maximum dose is 1.5 mg.

Use in patients with impaired renal and hepatic function: No dosage adjustment is recommended in patients with renal and hepatic dysfunction.

Overdose

There is no known antidote to Palonosetron. Overdose should be managed with supportive care.

Pharmaceutical Precautions

Store at below 30^0C in a dry place protected from light. Keep out of reach of children.

Commercial Packs

Palo**tic** 0.5 Tablet: Each box contains 2 x 10 tablets in Alu-Alu blister pack.

Palo**tic** 0.25 Injection: Each box contains 1 x 3 ampoules in blister pack.

Palo**tic** 0.075 Injection: Each box contains 1 x 5 ampoules in blister pack.

Manufactured by :

POPULAR

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