Palorex

Palonosetron

Composition:

Palorex Tablet: Each film coated tablet contains Palonosetron HCl INN equivalent to Palonosetron 0.5 mg.

Description:

Palonosetron is a highly selective second generation 5-HT_3 receptor antagonist which exhibits allosteric binding and positive cooperativity thus induces conformational changes in the receptor. Another hypothetical feature is receptor internalization, by which Palonosetron decreases the overall number of receptor sites available to serotonin. Palonosetron has at least 30-fold higher binding affinity for the 5-HT_3 receptor than older 5-HT_3 recptor antagonists.

Pharmacokinetics:

Following oral administration, Palonosetron is well absorbed with its absolute bioavailability reaching 97%. Mean time to reach the maximum concentration ranged from 3.8 to 5.7 hours after oral dosing. A high fat meal does not affect the C_{max} and AUC of oral Palonosetron. Palonosetron is eliminated by multiple routes in which approximately 42% of the administered dose excreted in urine as unchanged condition.

Indications:

Palorex is indicated for:

- Prevention of both acute and delayed nausea and vomiting.
- Prevention of acute nausea and vomiting associated with moderately emetogenic cancer chemotherapy.
- Prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy.
- Prevention of postoperative nausea and vomiting (PONV) for up to 24 hours following surgery.

Dosage & Administration:

Palorex can be taken with or without food.

Usual dosage

Adult tablet dosage: One 0.5 mg tablet/day

Chemotherapy-induced Nausea and Vomiting

Adult tablet dosage: One 0.5 mg tablet administered approximately one hour prior to the start of Chemotherapy.

OR AS DIRECTED BY THE PHYSICIAN.

Use in special population:

Pregnancy: Pregnancy **Category B**. Adequate and well controlled studies of palonosetron has not been conducted in pregnant woman. However, Palonosetron should be used during pregnancy only if clearly needed.

Lactation: It is not known whether Palonosetron is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: US FDA approved palonosetron for chemotherapy induce nausea and vomiting in children aged 1 month to less than 17 years.

Geriatric Use: No dose adjustment or special monitoring is required for geriatric patients.

Contraindications:

Palonosetron is contraindicated in patients known to have hypersensitivity to the drug or any of its components. Hypersensitivity reactions may occur in patients who have exhibited hypersensitivity to other 5-HT_3 receptor antagonists.

Drug Interactions:

Palonosetron is not an inhibitor or inducer of CYP system. Therefore, the potential for clinically significant drug interactions with Palonosetron appears to be low.

Side Effects:

Common: Diarrhoea, constipation, headache & dizziness.

Less common: Dyspepsia, abdominal pain, dry mouth, flatulence, changes in blood pressure, tachycardia, bradycardia, arrhythmia, anorexia, motion sickness, influenza-like symptoms, urinary retention, tinnitus, rash etc.

Overdose:

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

Storage Condition:

Store in a cool & dry place, protect from light. Keep out of the reach of children.

Presentation:

Palorex Tablet: Each commercial box contains 2x10's tablets in Alu-Alu blister pack.

Manufactured by:

Julphar Bangladesh Ltd.

Sreepur, Gazipur, Bangladesh.