

PalosetTM

Palonosetron

Composition

PalosetTM 0.075 Injection: Each 1.5 ml ampoule contains Palonosetron 0.075 mg as Palonosetron hydrochloride USP.

PalosetTM Tablet: Each Tablet contains Palonosetron 0.5 mg as Palonosetron hydrochloride USP.

Pharmacology

Nausea and Vomiting is usually produced by chemotherapeutic agents by releasing serotonin from the enterochromaffin cells of the small intestine. The released serotonin (5-HT) then activates 5-HT₃ receptors located on vagal afferents 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 serotonin (5-HT) in a cascade of neuronal events involving both the central nervous system and the gastrointestinal tract. The 5-HT₃ receptor has been demonstrated to selectively participate in the emetic response. Palonosetron is a 5-HT₃ receptor antagonist with a strong binding affinity for this receptor and little or no affinity for other receptors. So by binding with this receptor palonosetron inhibits binding of serotonin to this receptor and also inhibits vomiting reflex.

INDICATIONS

PalosetTM 0.075 IV Injection is indicated for:

- Prevention of postoperative nausea and vomiting (PONV) for up to 24 hours following surgery.

PalosetTM Tablet is indicated for:

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

DOSAGE AND ADMINISTRATION

Chemotherapy-Induced Nausea and Vomiting

PalosetTM Tablet

A single tablet should be used only on the day of chemotherapy. If symptoms persist, can be used once in a day or once every two days for three doses on consecutive days.

Postoperative Nausea and Vomiting

PalosetTM 0.075 IV Injection

Adults: A single 0.075 mg I.V. dose administered over 10 seconds immediately before the induction of anesthesia.

Children (From 1 month to 17 years): Not recommended.

Instructions for I.V. Administration

- It should not be mixed with other drugs
- Flush the infusion line with normal saline before and after administration
- Parenteral drug products should be inspected visually for particulate matter and discoloration before administration

Contraindication

Palonosetron is contraindicated in patients known to have hypersensitivity to the drug or any of its components.

Side Effects

The most common side effects of Palonosetron in chemotherapy-induced nausea and vomiting are headache and constipation.

The most common side effects of Palonosetron in postoperative nausea and vomiting are QT prolongation, bradycardia, headache and constipation.

Precaution

Hypersensitivity reactions, including anaphylaxis, have been reported with or without known hypersensitivity to other selective 5-HT₃ receptor antagonists.

Pregnancy & lactation

Pregnancy Category-B

There are no adequate and well-controlled studies in pregnant women. Palonosetron should be used during pregnancy only if clearly needed. It is not known whether Palonosetron is excreted in human milk.

Drug interaction

No potential or clinically significant drug interactions with Palonosetron was found.

Storage

Protect from light & moisture, store below 25° C. Keep all the medicines out of the reach of children.

How supplied

PalosetTM 0.075 Injection: Each box contains 5 ampoules in blister pack.

PalosetTM Tablet: Each box contains 20 tablets in blister pack.

Manufactured by:



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH