Palosis®

Palonosetron Hydrochloride USP Tablet, Capsule and Injection

DESCRIPTION

Palosis® is a preparation of Palonosetron Hydrochloride. Palonosetron is a 5-HT3 receptor antagonist with a strong binding affinity for this receptor and little or no affinity for other receptors. Cancer chemotherapy may be associated with a high incidence of nausea and vomiting, particularly when certain agents, such as Cisplatin are used. 5HT3 receptors are located on the nerve terminals of the vagus in the periphery and centrally in the chemoreceptor trigger zone of the area postrema. 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-HT3 receptors located on vagal afferents to initiate the vomiting reflex.

INDICATIONS

Palosis® is indicated in adults for:

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

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

• Dosage for Adult:

One 0.5 mg Tablet or Capsule administered approximately one hour prior to the start of Chemotherapy.

Palosis® can be taken with or without food.

Age	Dose	Infusion Time
Adults	0.25 mg x 1	Infuse over 30 seconds beginning approx. 30 min before the start of chemo
Pediatrics (1 month to less than 17 years)	20 micrograms per kilogram (max 1.5 mg) x 1	Infuse over 15 minutes beginning approx. 30 min before the start of chemo

Postoperative Nausea and Vomiting:

- Adult Dosage: a single 0.075 mg intravenous dose administered over 10 seconds immediately before the induction of anesthesia.

CONTRAINDICATIONS

Palosis® is contraindicated in patients known to have hypersensitivity to the drug.

SIDE EFFECTS

- Headache
- Constipation

WARNING AND PRECAUTION

Hypersensitivity reactions may occur in patients who have exhibited hypersensitivity to other 5-HT3 receptor antagonists. Serotonin syndrome has been reported with 5-HT3 receptor antagonists alone but particularly with concomitant use of serotonergic drugs.

USE IN PREGNANCY AND LACTATION

Pregnancy Category B. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, Palonosetron should be used during pregnancy only if clearly needed. 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 and the potential for tumorigenicity shown for Palonosetron in the rat carcinogenicity study, 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.

PHARMACEUTICAL PRECAUTION

Do not store above 30 ˚C temperature. Keep away from light and wet place. Keep out of reach of the children.

PACKAGING

Palosis® Capsule:

Box containing 4 strips of 5 capsules each. Each capsule contains Palonosetron Hydrochloride USP equivalent to Palonosetron 0.5 mg.

Palosis® Tablet:

Box containing 2 strips of 10 tablets each. Each film coated tablet contains Palonosetron Hydrochloride USP equivalent to Palonosetron 0.5 mg.

Palosis® 0.075 IV Injection:

Box containing 1 strip of 5 ampoules. Each ampoule contains Palonosetron Hydrochloride USP equivalent to Palonosetron 0.075 mg with fill volume of 1.5 mL.

Palosis® 0.25 IV Injection:

Box containing 1 strip of 3 ampoules. Each ampoule contains Palonosetron Hydrochloride USP equivalent to Palonosetron 0.25 mg with fill volume of 5 mL.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

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