Palotron

Palonosetron

COMPOSITION

Palotron 0.25 mg/5 ml IV Injection: Each 5 ml ampoule contains sterile solution of Palonosetron Hydrochloride USP equivalent to Palonosetron 0.25 mg.

Palotron 0.075 mg/1.5 ml IV Injection: Each 1.5 ml ampoule contains sterile solution of Palonosetron Hydrochloride USP equivalent to Palonosetron 0.075 mg.

PHARMACOLOGY

Palonosetron is a 5-HT3 receptor antagonist with a strong binding affinity for this receptor. Chemotherapeutic agents produce nausea and vomiting by releasing serotonin from the enterochromaffin cells of the small intestine and the released serotonin then activates 5-HT3 receptors initiating the vomiting reflex. Postoperative nausea and vomiting are triggered by the release of 5-HT in a cascade of neuronal events involving the central nervous system and the gastrointestinal tract.

INDICATIONS

Adults:

- 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 for up to 24 hours following surgery. Efficacy beyond 24 hours has not been demonstrated.

Pediatric patients (1 month to less than 17 years):

Prevention of acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy (highly emetogenic cancer chemotherapy).

DOSAGE AND ADMINISTRATION

Chemotherapy induced nausea and vomiting

Adults: 0.25 mg of one dose. Infuse over 30 seconds beginning approx. 30 minutes before the start of chemotherapy.

Pediatrics (1 month to less than 17 years): 20 micrograms per kilogram (max 1.5 mg) of one dose. Infuse over 15 minutes beginning approx. 30 min before the start of chemotherapy.

Prevention of postoperative nausea and vomiting

A single 0.075 mg intravenous dose for adults administered over 10 seconds immediately before the induction of anesthesia.

CONTRAINDICATIONS

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

WARNING & PRECAUTION

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

SIDE EFFECTS

The most common side effects of chemotherapy-induced nausea and vomiting in adults (incidence ≥5%) are headache and constipation. The most common side effects of postoperative nausea and vomiting (incidence ≥ 2%) are QT prolongation, bradycardia, headache and constipation.

USE IN PREGNANCY & LACTATION

There are no adequate and well controlled studies in pregnant women. Thus, it should not be used without concern of physicians. It is not known whether it is excreted in human milk. So, breastfeeding should be considered along with the mother's clinical need and any potential adverse effect on the breastfed infant.

USE IN CHILDREN & ADOLESCENTS

Chemotherapy-induced nausea and vomiting pediatric use: Safety and effectiveness in neonates (less than 1 month of age) have not been established.

Postoperative nausea and vomiting: Safety and Effectiveness in patients below the age of 18 years have not been established.

DRUG INTERACTIONS

Concomitant use with serotonergic drugs (SSRIs, SNRIs) develops serotonin syndrome; If symptoms occur, discontinue Palonosetron Hydrochloride Injection and initiate supportive treatment.

OVERDOSAGE

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

STORAGE

Store below 30°C temperature in a cool & dry place. Protect from light. Do not freeze. Keep out of the reach of children.

HOW SUPPLIED

Palotron 0.25 mg/5 ml IV Injection: Each box contains 1 ampoule in Alu-PVC blister pack.

Palotron 0.075 mg/1.5 ml IV Injection: Each box contains 1 ampoule in Alu-PVC blister pack.

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.

NIPRO JMI Pharma

14020000373/00