POSFREA®
(palonosetron) Injection

Ordering Information

To order POSFREA® (palonosetron) Injection, please contact one of these authorized specialty distributors and use the appropriate order #:

0.25 mg/5 mL (0.05 mg/mL)
NDC: 83831-0105-01

Institutions/Hospitals	0.25 mg/5 mL (0.05 mg/mL)
Cardinal Health Specialty	5945779
CENCORA - ASD Healthcare	10292116
Physician Offices	**0.25 mg/5 mL (0.05 mg/mL)**
Cardinal Health Specialty	5945779
Oncology Supply	10292154
McKesson Specialty Health	5018368

UNIQUE J-CODE

J2468

Highlights[1]

- Free from disodium edetate (EDTA)
- Free from sodium citrate
- Not made with natural rubber
- Unique J-Code: J2468

Please see Indications and Important Safety Information on pages 2 to 3 and full Prescribing Information for POSFREA®.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

POSFREA® is indicated in adults for prevention of:

- acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).
- acute nausea and vomiting associated with initial and repeat courses highly emetogenic cancer chemotherapy (HEC).
- postoperative nausea and vomiting (PONV) for up to 24 hours following surgery. Efficacy beyond 24 hours has not been demonstrated.

As with other antiemetics, routine prophylaxis is not recommended in patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and vomiting must be avoided during the postoperative period, POSFREA is recommended even where the incidence of postoperative nausea and/or vomiting is low.

POSFREA is indicated in pediatric patients 1 month to less than 17 years of age for prevention of:

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

POSFREA is contraindicated in patients known to have hypersensitivity to palonosetron or any of its components.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis and anaphylactic shock, have been reported with administration of palonosetron. These reactions occurred in patients with or without known hypersensitivity to other 5-HT_3 receptor antagonists. If hypersensitivity reactions occur, discontinue POSFREA and initiate appropriate medical treatment. Do not reinitiate POSFREA in patients who have previously experienced symptoms of hypersensitivity.

Serotonin Syndrome

The development of serotonin syndrome has been reported with 5-HT_3 receptor antagonists. Most reports have been associated with concomitant use of serotonergic drugs (e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors, mirtazapine, fentanyl, lithium, tramadol, and intravenous methylene blue). Some of the reported cases were fatal. Serotonin syndrome occurring with overdose of another 5-HT_3 receptor antagonist alone has also been reported. The majority of reports of serotonin syndrome related to 5-HT_3 receptor antagonist use occurred in a post- anesthesia care unit or an infusion center.

Symptoms associated with serotonin syndrome may include the following combination of signs and symptoms: mental status changes (e.g., agitation, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, with or without gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea).

Please see Important Safety Information on pages 2 and 3 and full Prescribing Information for POSFREA.®

IMPORTANT SAFETY INFORMATION (CONTINUED)

Patients should be monitored for the emergence of serotonin syndrome, especially with concomitant use of POSFREA and other serotonergic drugs.

ADVERSE REACTIONS

Most common adverse reactions in

- chemotherapy-induced nausea and vomiting in adults (≥5%) are: headache and constipation.
- postoperative nausea and vomiting (≥ 2%) are: QT prolongation, bradycardia, headache, and constipation.

DRUG INTERACTIONS

Serotonergic Drugs: Serotonin syndrome (including altered mental status, autonomic instability, and neuromuscular symptoms) has been described following the concomitant use of 5-HT_3 receptor antagonists and other serotonergic drugs, including selective serotonin reuptake inhibitors (SSRIs) and serotonin and noradrenaline reuptake inhibitors (SNRIs). Monitor for the emergence of serotonin syndrome. If symptoms occur, discontinue POSFREA and initiate supportive treatment.

USE IN SPECIFIC POPULATIONS

Pediatric Use:

Chemotherapy-Induced Nausea and Vomiting (CINV): Safety and effectiveness of POSFREA have been established in pediatric patients aged 1 month to less than 17 years for the prevention of acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including HEC.

Postoperative Nausea and Vomiting (PONV): Safety and effectiveness have not been established in pediatric patients for PONV.

OVERDOSAGE

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

Please see full Prescribing Information of POSFREA

To report SUSPECTED ADVERSE REACTIONS, contact Avyxa Pharma, LLC at 1-888-520-0954 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.