

Reference number(s)
10-H

Quantity Limit Palonosetron Antiemetics

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Palonosetron Hydrochloride	palonosetron hydrochloride
palonosetron hydrochloride (brand unavailable)	palonosetron hydrochloride
Posfrea	palonosetron hydrochloride

Indications

FDA-approved Indications

Palonosetron Hydrochloride Injection 5 mL single-dose vial

Palonosetron hydrochloride injection 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 of 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, palonosetron hydrochloride is recommended even where the incidence of postoperative nausea and/or vomiting is low.

Palonosetron hydrochloride injection is indicated in pediatric patients 1 month to less than 17 years of age for

Reference number(s)
10-H

prevention of:

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

Palonosetron Hydrochloride Injection 2 mL single-dose vial

Palonosetron Hydrochloride (HCl) Injection is indicated for:

- 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

Posfrea

Chemotherapy-Induced Nausea and Vomiting in Adults

Posfrea is indicated for:

- 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

Postoperative Nausea and Vomiting in Adults

Posfrea is indicated for prevention of 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.

Initial Limit Quantity

Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength.

The duration of 21 days is used for a 28-day fill period to allow time for refill processing.

These drugs are for short-term acute use; therefore, the intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3 month supplies filled.

Drug	4 Week Limit	12 Week Limit
Palonosetron HCl Injection 0.25 mg/2 mL	4 mL / 21 days	Does Not Apply
palonosetron HCl Injection 0.25 mg/5 mL	10 mL / 21 days	Does Not Apply

Reference number(s)
10-H

Drug	4 Week Limit	12 Week Limit
Posfrea (palonosetron HCl Injection) 0.25 mg/5 mL	10 mL / 21 days	Does Not Apply
Posfrea (palonosetron HCl Injection) 0.075 mg/1.5 mL	12 mL / 21 days	Does Not Apply

References

1. Palonosetron Injection [package insert]. Princeton, NJ: Dr Reddy's; August 2020.
2. Palonosetron Hydrochloride [package insert]. Eatontown, NJ: West Ward Pharmaceuticals, Inc.; October 2017.
3. Posfrea Injection [package insert]. New Jersey: Avyxa Pharma, LLC; July 2024.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 11, 2024.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/11/2024).
6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Antiemesis. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed November 30, 2023.