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| Reference number(s) |
| 16-J |

Post Limit Prior Authorization

Antiemetic 5-HT3

Antiemetic Agents – 5-HT3 Antagonists

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 | Dosage Form |
|---|------------------------------|----------------------------------|
| Anzemet | dolasetron mesylate | all |
| granisetron hydrochloride (brand unavailable) | granisetron hydrochloride | all |
| ondansetron (brand unavailable) | ondansetron | oral disintegrating tablet |
| ondansetron hydrochloride (brand unavailable) | ondansetron hydrochloride | tablet, oral solution, injection |
| Palonosetron Hydrochloride | palonosetron hydrochloride | all |
| palonosetron hydrochloride (brand unavailable) | palonosetron hydrochloride | all |
| Posfrea | palonosetron hydrochloride | all |
| Sancuso | granisetron | transdermal system |
| Sustol | granisetron extended-release | injection |

Indications

FDA-approved Indications

Anzemet Tablets

Anzemet tablets are indicated for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, including initial and repeat courses in adults and children 2 years and older.

Granisetron Hydrochloride

Granisetron Hydrochloride Tablets

Granisetron hydrochloride tablets USP are indicated for the prevention of:

- Nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin.
- Nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation.

Granisetron Hydrochloride Injection:

Granisetron hydrochloride injection, USP is a serotonin-3 (5-HT₃) receptor antagonist indicated for:

- The prevention of nausea and/or vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin.
- The prevention and treatment of postoperative nausea and vomiting in adults. 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/or vomiting must be avoided during the postoperative period, granisetron hydrochloride injection USP is recommended even where the incidence of postoperative nausea and/or vomiting is low.

Ondansetron Injection

Prevention of Nausea and Vomiting Associated with Initial and Repeat Courses of Emetogenic Cancer Chemotherapy

Ondansetron injection is indicated for the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including high-dose cisplatin. Ondansetron injection is approved for patients aged 6 months and older.

Prevention of Postoperative Nausea and/or Vomiting

Ondansetron injection is indicated for the prevention of postoperative nausea and/or vomiting. As with other antiemetics, routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients in whom nausea and/or vomiting must be avoided postoperatively, ondansetron injection is recommended even when the incidence of postoperative nausea and/or vomiting is low. For patients who do not receive prophylactic ondansetron injection and experience nausea and/or vomiting postoperatively, ondansetron injection may be given to prevent further episodes. Ondansetron injection is approved for patients aged 1 month and older.

Ondansetron Tablets, ODT, and Oral Solution

Ondansetron tablets, orally disintegrating tablets, and oral solution are indicated for the prevention of nausea and vomiting associated with:

- highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m².
- initial and repeat courses of moderately emetogenic cancer chemotherapy.
- radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.

Ondansetron tablets, orally disintegrating tablets, and oral solution are also indicated for the prevention of postoperative nausea and/or vomiting.

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.

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 months 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.

Posfrea

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 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, Posfrea is recommended even where the incidence of postoperative nausea and/or vomiting is low.

Posfrea is indicated in pediatric patients 1 months 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.

Sancuso Transdermal System

Sancuso is indicated for the prevention of nausea and vomiting in adults receiving moderately and/or highly emetogenic chemotherapy regimens of up to 5 consecutive days duration.

Sustol Extended-Release Injection

Sustol is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.

Compendial Uses:

- Treatment and/or prophylaxis of radiation-induced nausea and vomiting¹⁴

Compendial Uses Ondansetron Only

- Hyperemesis Gravidarum^{14,15}

Coverage Criteria

Hyperemesis Gravidarum

Authorization may be granted for the diagnosis of Hyperemesis Gravidarum when ALL of the following criteria are met:

- The patient is pregnant.
- The patient has a documented risk for hospitalization.
- The request is for ondansetron.
- The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following medications: dimenhydrinate (Dramamine), diphenhydramine (Benadryl), doxylamine/pyridoxine delayed-release (Diclegis), doxylamine/pyridoxine extended-release (Bonjesta), metoclopramide (Reglan), promethazine (Phenergan), trimethobenzamide (Tigan), vitamin B6, vitamin B6 in combination with doxylamine.

Radiation Therapy or Moderate to Highly Emetogenic Chemotherapy

Authorization may be granted when the patient is receiving radiation therapy or moderate to highly emetogenic chemotherapy.

Duration of Approval (DOA):

- 16-J: DOA: 6 months

References

1. Anzemet Tablets [package insert]. Parsippany, NJ: Validus Pharmaceuticals LLC; June 2021.
2. Granisetron Hydrochloride Tablet [package insert]. Berlin, CT: Breckenridge Pharmaceutical, Inc.; January 2024.
3. Granisetron Hydrochloride Injection [package insert]. E. Windsor, NJ: AuroMedics Pharma LLC; December 2021.
4. Ondansetron Injection [package insert]. Deerfield, IL: Baxter Health Corporation; February 2022.
5. Ondansetron Tablets [package insert]. Saddle Brook, NJ: Rising Health, LLC; July 2022.
6. Ondansetron Orally Disintegrating Tablets [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; November 2021.
7. Ondansetron Oral Solution [package insert]. Memphis, TN: Northstar Rx LLC; December 2021.
8. Palonosetron Injection [package insert]. Princeton, NJ: Dr Reddy's; August 2020.
9. Palonosetron Hydrochloride [package insert]. Eatontown, NJ: West-Ward Pharmaceuticals, Inc; October 2017.
10. Posfrea Injection [package insert]. New Jersey: Avyxa Pharma, LLC; July 2024.
11. Sancuso Patch [package insert]. Nashville, TN: Cumberland Pharmaceuticals, Inc.; July 2024.
12. Sustol Injection [package insert]. San Diego, CA: Heron Therapeutics, Inc.; May 2023.
13. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed December 10, 2024.
14. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 12/10/2024).
15. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Antiemesis. Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed November 29, 2024.
16. Hesketh P, Kris M, Basch E, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol* 2020;38:2782-2797.
17. American College of Obstetricians and Gynecologists Practice Bulletin No.189. Clinical Management Guidelines for Obstetrician-Gynecologists. Nausea and Vomiting of Pregnancy. *Obstet Gynecol* 2018;131(1):e15-e30.
18. American Cancer Society. How is Chemotherapy Used to Treat Cancer? <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy/how-is-chemotherapy-used-to-treat-cancer.html>. November 2019. Accessed November 29, 2024.