

Reference number(s) 259-H

Quantity Limit Ondansetron Products 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	Dosage Form
ondansetron (brand unavailable)	ondansetron	oral disintegrating tablet
ondansetron hydrochloride (brand unavailable)	ondansetron hydrochloride	tablet, oral solution, injection

Indications

FDA-approved Indications

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

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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.

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
Ondansetron 2 mg / mL injection	20 mL / 21 days	Does Not Apply
Ondansetron 24 mg tablets	2 tablets / 21 days	Does Not Apply
Ondansetron 4 mg and 8 mg tablets/ODT	18 tablets / 21 days	Does Not Apply
Ondansetron 16 mg ODT	9 tablets / 21 days	Does Not Apply
Ondansetron 4mg / 5mL oral solution	200 mL / 21 days	Does Not Apply

References

- 1. Ondansetron Injection [package insert]. Deerfield, IL: Baxter Health Corporation; February 2022.
- 2. Ondansetron Tablets [package insert]. Saddle Brook, NJ: Rising Health, LLC; July 2022.
- 3. Ondansetron Orally Disintegrating Tablets [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; April 2024.
- 4. Ondansetron Orally Disintegrating Tablets 16mg [package insert]. New Brunswick, NJ: Lifsa Drugs LLC; June 2024.
- 5. Ondansetron Oral Solution [package insert]. Memphis, TN: Northstar Rx LLC; January 2022.
- 6. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed December 10, 2024.
- 7. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 12/10/2024).
- 8. 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 27, 2024.