



Prior Authorization DRUG Guidelines

VARUBI (Rolapitant)

Effective Date:4/23/19

Date Developed: 2/26/19 by R. Sterling

Last Approval Date: 2/18/20, 2/2/21, 8/3/21, 2/1/22, 1/31/23, 2/13/24, 2/18/25,
2/20/26

Varubi is used alone or in combination with other agents to prevent delayed nausea and vomiting associated with emetogenic chemotherapy by selectively and competitively inhibiting the substance P/neurokinin 1 (NK1) receptor.

Pre-Authorization Criteria:

Prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy in combination with other antiemetic agents

NOTE: IV Varubi has been discontinued in the United State

NOTE: Prior to use of Varubi, VCHCP will require documentation of a significant failure of alternative medications* and/or a compelling reason submitted by the requesting physician to use Varubi as a primary therapeutic agent.

***Other therapeutics agents:** ondansetron, metoclopramide; dexamethasone; olanzepine; promethazine; prochlorperazine; benzodiazepines; alternative medicines (cannabinoids e.g. dronabinol/Marinol; ginger; acupuncture)

Precautions: Avoid use in patients with severe hepatic impairment; Contraindicated in pediatric patients <2 years of age; Significant drug interactions exist, requiring dose/frequency adjustment or avoidance. Consult drug interactions database for more information; Varubi is a moderate CYP2D6 inhibitor (avoid in combination with thioridazine and pimozide).

Dose: 180 mg as a single dose administered within 2 hours prior to initiation of chemotherapy on day 1 only (in combination with dexamethasone given on days 1, 2, 3, and 4 and a 5-HT₃ receptor antagonist given on day 1)

Dosing Forms:

Tablet: 90 mg

The Drug Quantity limit is 2 tablets.



References

Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: ASCO guideline update. *J Clin Oncol*. 2020;38(24):2782-2797. doi:10.1200/JCO.20.01296

Rapoport BL, Chasen MR, Gridelli C, et al. Safety and efficacy of rolapitant for prevention of chemotherapy-induced nausea and vomiting after administration of cisplatin-based highly emetogenic chemotherapy in patients with cancer: two randomised, active-controlled, double-blind, phase 3 trials. *Lancet Oncol*. 2015;16(9):1079-1089

Roila F, Molassiotis A, Herrstedt J, et al; participants of the MASCC/ESMO Consensus Conference Copenhagen 2015. 2016 MASCC and ESMO guideline update for the prevention of chemotherapy- and radiotherapy-induced nausea and vomiting and of nausea and vomiting in advanced cancer patients. *Ann Oncol*. 2016;27(suppl 5):v119-v133.

Schwartzberg LS, Modiano MR, Rapoport BL, et al. Safety and efficacy of rolapitant for prevention of chemotherapy-induced nausea and vomiting after administration of moderately emetogenic chemotherapy or anthracycline and cyclophosphamide regimens in patients with cancer: a randomised, active-controlled, double-blind, phase 3 trial. *Lancet Oncol*. 2015;16(9):1071-1078.

Varubi (rolapitant) [prescribing information]. Deerfield, IL: TerSera Therapeutics LLC; August 2020.

Schwartzberg LS, Modiano MR, Rapoport BL, et al. Safety and efficacy of rolapitant for prevention of chemotherapy-induced nausea and vomiting after administration of moderately emetogenic chemotherapy or anthracycline and cyclophosphamide regimens in patients with cancer: a randomised, active-controlled, double-blind, phase 3 trial. *Lancet Oncol*. 2015;16(9):1071-1078.

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| Revision Date | Content Revised (Yes/No) | Contributors | Review/Revision Notes |
|---------------|--------------------------|---|---|
| 2/18/20 | No | Howard Taekman, MD; Robert Sterling, MD | Annual review |
| 2/2/21 | No | Howard Taekman, MD; Robert Sterling, MD | Annual review |
| 8/3/21 | Yes | Howard Taekman, MD; Robert Sterling, MD | Numerous changes, additions, formatting; references added (none were there) |
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| 2/18/25 | Yes | Howard Taekman, MD; Robert Sterling, MD | Removed some notes under Preauthorization sections. Added "Precautions: Avoid use in patients with severe hepatic impairment; Contraindicated in pediatric patients <2 years of age; Significant drug interactions exist, requiring dose/frequency adjustment or avoidance. Consult drug interactions database for more information; Varubi is a moderate CYP2D6 inhibitor (avoid in combination with thioridazine and pimoziide)." |
| 2/20/26 | No | Robert Sterling, MD | Annual Review |