

# The Medical Letter®

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### IN THIS ISSUE

In Brief: Severe Hypersensitivity Reactions with Rolapitant IV Emulsion (*Varubi*)..... p 24

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### IN BRIEF

#### Severe Hypersensitivity Reactions with Rolapitant IV Emulsion (*Varubi*)

The FDA has warned that the IV emulsion formulation of the substance P/neurokinin 1 (NK1) receptor antagonist rolapitant (*Varubi*) has been associated in postmarketing reports with serious hypersensitivity reactions including anaphylaxis and anaphylactic shock.<sup>1</sup> Rolapitant was approved by the FDA as an oral tablet in 2015 for adjunctive prevention of delayed nausea and vomiting associated with cancer chemotherapy in adults<sup>2</sup>; the IV emulsion formulation of the drug was approved for the same indication in 2017.

The reported hypersensitivity reactions occurred during or shortly after infusion of rolapitant IV emulsion, and hospitalization was required in some cases. Rolapitant emulsion contains soybean oil; patients with known allergies to legumes or other related allergens may be at increased risk of developing a hypersensitivity reaction. IV fosaprepitant (*Emend*), the other parenteral substance P/NK1 inhibitor formulation approved by the FDA, does not contain soybean oil, but has also been associated with serious hypersensitivity reactions.

Patients with a history of hypersensitivity to soybean oil should not be treated with IV rolapitant. Those with known allergies to legumes or other related allergens should be monitored for signs of hypersensitivity during and following infusion of the emulsion. If a serious reaction occurs, use of rolapitant IV emulsion should be permanently discontinued.

1. FDA. *Varubi* (rolapitant) injectable emulsion: health care provider letter – anaphylaxis and other serious hypersensitivity reactions. January 16, 2018. Available at: [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedical-Products/ucm592592.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedical-Products/ucm592592.htm). Accessed January 18, 2018.
2. Rolapitant (*Varubi*) for prevention of delayed chemotherapy-induced nausea and vomiting. *Med Lett Drugs Ther* 2016; 58:17.

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