



TESARO, INC. | 1 000 WINTER STREET, SUITE 3300 | WALTHAM, MA 02451

January 2018

**IMPORTANT DRUG WARNING
IMPORTANT PRESCRIBING INFORMATION**

Subject: Anaphylaxis, anaphylactic shock and other serious hypersensitivity reactions associated with use of VARUBI® (rolapitant) injectable emulsion

Dear Health Care Provider:

The purpose of this letter is to inform you of important safety information for VARUBI® (rolapitant) injectable emulsion, a substance P/neurokinin (NK-1) receptor antagonist indicated for the prevention of delayed nausea and vomiting associated with cancer chemotherapy in adults.

Anaphylaxis, Anaphylactic Shock and Other Serious Hypersensitivity Reactions Associated with Use of VARUBI® (rolapitant) Injectable Emulsion

Anaphylaxis, anaphylactic shock and other serious hypersensitivity reactions have been reported in the postmarketing setting, some requiring hospitalization. These reactions have occurred during or soon after the infusion of VARUBI® (rolapitant) injectable emulsion. Most reactions have occurred within the first few minutes of administration. Symptoms of anaphylaxis can include wheezing or difficulty breathing; swelling of the face or throat; hives or flushing; itching; abdominal cramping, abdominal pain or vomiting; back pain or chest pain; hypotension or shock.

Prescriber Action

Healthcare professionals must be vigilant for signs of hypersensitivity or anaphylaxis in all patients receiving VARUBI® (rolapitant) injectable emulsion, both during and following its administration.

It is advised that Healthcare professionals consult with patients to determine if the patient is hypersensitive to any component of the product (including soybean oil). Furthermore, as cross reactions to other allergens is possible, patients with known allergies to legumes or other related allergens should be monitored closely. Patients with a potential hypersensitivity should not be administered VARUBI® (rolapitant) injectable emulsion.



TESARO, INC. | 1000 WINTER STREET, SUITE 3300 | WALTHAM, MA 02451

Appropriate treatment should be available for immediate use in the event of an anaphylactic reaction during treatment with VARUBI[®] (rolapitant) injectable emulsion.

If anaphylaxis or any other serious hypersensitivity/infusion reaction occurs,

- administration of VARUBI[®] (rolapitant) injectable emulsion should be stopped immediately.
- appropriate medical management (including epinephrine and or antihistamines) should be initiated, and
- VARUBI[®] (rolapitant) injectable emulsion should be permanently discontinued.

Important Prescribing Information

The Prescribing Information has been updated to reflect the new safety information.

Other drugs should not be added to the VARUBI[®] (rolapitant) Injectable Emulsion vial until compatibility can be further evaluated. Please refer to the Prescribing Information for additional information on Dosing and Administration.

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events in patients taking VARUBI (rolapitant) injectable emulsion to TESARO at 1-844-4-TESARO (1-844-483-7276). You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

You may also contact TESARO's medical information department at 1-844-4-TESARO (1-844-483-7276) if you have any questions about the information contained in this letter or the safe and effective use of VARUBI[®] (rolapitant) injectable emulsion.

This letter is not intended as a complete description of the benefits and risks related to the use of VARUBI[®] (rolapitant) injectable emulsion. Please refer to the full prescribing information and approved patient information.

Sincerely,

Martin Huber, M.D.
Chief Medical Officer
TESARO, Inc.