

POMALIDOMIDE RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Education and Prescribing Safety Kit

About Pomalidomide

Pomalidomide, in combination with dexamethasone, is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

Risks of Pomalidomide

Pomalidomide has a Boxed Warning for embryo-fetal toxicity and thromboembolic events, including deep venous thrombosis (DVT) and pulmonary embolism (PE), myocardial infarction and stroke.

Due to the fact that it is an analogue of thalidomide, a known teratogen, pomalidomide is contraindicated in pregnant females or females capable of becoming pregnant. Females who can get pregnant may be treated with pomalidomide if they take adequate precautions to avoid pregnancy. Deep Venous Thrombosis (DVT), Pulmonary Embolism (PE), myocardial infarction and stroke occur in patients with multiple myeloma treated with pomalidomide.

This is not a comprehensive description of risks associated with the use of pomalidomide. Please see Prescribing Information¹, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

Prescriber Quick Reference Guide

1. The prescriber provides comprehensive counseling.
 2. The prescriber verifies negative pregnancy test for all female patients of reproductive potential.
 3. The prescriber completes the **Patient-Physician Agreement Form** with each patient and sends to REMS Coordinating Center.
 4. Female patients complete initial mandatory confidential survey by:
 - Visiting www.PomalidomideREMSProgram.com
 - Calling the REMS Coordinating Center at 1-866-245-7925Male patients do not need to complete the initial survey.
- All patients must complete subsequent mandatory confidential surveys as outlined in the **Prescriber Guide**.
5. The prescriber completes mandatory confidential survey and receives authorization number by:
 - Visiting www.PomalidomideREMSProgram.com
 - Calling the REMS Coordinating Center at 1-866-245-7925
 6. The prescriber writes the pomalidomide prescription and includes the authorization number and patient risk category.
 7. The prescriber sends prescription to a certified pharmacy.

This flow sheet should be used only as a quick reference and only after reviewing all of the Pomalidomide REMS procedures.

Pomalidomide is only available under a restricted distribution program, the Pomalidomide REMS

¹ Please note, the enclosed materials include Prescribing Information from each generic pomalidomide manufacturers participating in the Pomalidomide REMS.