

# Pomalidomide REMS

Dear Prescriber:

## Enclosed are your Pomalidomide REMS education materials

The Pomalidomide REMS is pleased to provide you with the enclosed materials for use in the Pomalidomide REMS.

Important Information about the Pomalidomide REMS:

- To avoid embryo-fetal exposure, pomalidomide is only available under a restricted distribution program called the Pomalidomide REMS
- Pomalidomide is contraindicated in pregnant females and females capable of becoming pregnant. Females who can get pregnant may be treated with pomalidomide provided adequate precautions are taken to avoid pregnancy
- Male Patients: Clinical data has demonstrated the presence of pomalidomide in human semen. Male patients taking pomalidomide should not donate sperm. Males receiving pomalidomide must always use a latex or synthetic condom during any sexual contact with females who can get pregnant even if they have undergone a successful vasectomy
- Only prescribers and pharmacies certified with the Pomalidomide REMS can prescribe and dispense pomalidomide to patients who are enrolled and meet all the conditions of the Pomalidomide REMS

As a prescriber certified with the Pomalidomide REMS, please review and familiarize yourself with the contents of the enclosed Pomalidomide REMS Education and Prescribing Safety Kit:

- **Prescriber Materials**
  - [Prescriber Guide](#)
  - Prescribing Information\*
    - *\* Please note, the enclosed materials include Prescribing Information from each generic pomalidomide manufacturers participating in the Pomalidomide REMS.*
- **Patient Materials (Patient Resource Pack)**
  - [Patient Guide](#)
  - [Emergency Contraception Brochure](#)
  - Medication Guide\*
    - *\*Please note, the enclosed materials include the Medication Guide from each generic pomalidomide manufacturers participating in the Pomalidomide REMS.*

To order additional Patient Resource Packs, please call the REMS Coordinating Center at 1- 866-245-7925.

Sincerely,

The Pomalidomide REMS

## **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 of reproductive potential 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 Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.**