

Pomalyst REMS®

Program for Pomalyst® (pomalidomide) Education and Prescribing Safety

Dear Prescriber:

Enclosed are your POMALYST REMS® program education materials.

Celgene Corporation is pleased to provide you with the enclosed materials for use in the POMALYST REMS® program.

Important Information about the POMALYST REMS® program

- To avoid embryo-fetal exposure, POMALYST is only available under a special restricted distribution program called “POMALYST REMS®”
- Pomalidomide is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential 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 POMALYST should not donate sperm. Males receiving POMALYST must always use a latex or synthetic condom during any sexual contact with females of reproductive potential even if they have undergone a successful vasectomy
- Only prescribers and pharmacies certified with POMALYST REMS® can prescribe and dispense POMALYST to patients who are enrolled and meet all the conditions of the POMALYST REMS® program

As a prescriber certified in the POMALYST REMS® program, please review and familiarize yourself with the contents of the enclosed POMALYST REMS® Kit:

Prescriber Materials

- Prescriber Guide to POMALYST REMS® Program
- POMALYST Full Prescribing Information

Patient Materials (Patient Resource Pack)

- Patient Guide to POMALYST REMS® Program
- Emergency Contraception Brochure
- MEDICATION GUIDE

To order additional Patient Resource Packs, please call the Celgene Customer Care Center at 1-888-423-5436.

Sincerely,



Jay T. Backstrom, MD, MPH
Chief Medical Officer & Global Head
Regulatory Affairs

Enclosures

Risks of POMALYST® (pomalidomide)

POMALYST 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, POMALYST is contraindicated in pregnant females or females capable of becoming pregnant. Females of reproductive potential may be treated with POMALYST 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 POMALYST. Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.



Pomalyst REMS®



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