

PS-Pomalidomide REMS

Education and Counseling Checklist for Pharmacies

PS-Pomalidomide Risk Evaluation and Mitigation Strategy (REMS) education and prescribing safety

Authorization No.: _____ Confirmation No.: _____ Confirmation Date: _____
Pharmacy Name: _____
Pharmacy Address: _____
Counselor Name: _____ Work Phone: _____ Ext.: _____
Patient Name: _____ Date of Birth: _____
Risk Category: _____

Checklist for female patients of reproductive potential

- ☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

- ☐ Potential embryo-fetal toxicity
- ☐ Not taking pomalidomide if pregnant or breastfeeding
- ☐ Using **at the same time** at least 1 highly effective method—tubal ligation, intrauterine device (IUD), hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy—and at least 1 additional effective method of birth control—male latex or synthetic condom, diaphragm, or cervical cap—**every time they have sex with a male**, or abstaining from sex with a male
- ☐ Unacceptable methods of birth control are progesterone-only “mini-pills,” IUD Progesterone T, female condoms, natural family planning (rhythm method) or breastfeeding, fertility awareness, withdrawal, and cervical shield (a cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception)
- ☐ Continuing to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking pomalidomide, while taking pomalidomide, during dose interruptions, and for at least 4 weeks after stopping pomalidomide **every time they have sex with a male**, or abstaining from sex with a male
- ☐ Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks
- ☐ The need to stop taking pomalidomide right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately
- ☐ Possible side effects include deep vein thrombosis, pulmonary embolism, myocardial infarction, and stroke
- ☐ Not sharing pomalidomide capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood while taking pomalidomide (including dose interruptions) and for 4 weeks after stopping pomalidomide
- ☐ Not breaking, chewing, or opening pomalidomide capsules
- ☐ Instructions on pomalidomide dose and administration

Milligram (mg) Strength _____ Number of Capsules Dispensed _____

FEMALE CHILDREN (<18 YEARS OF AGE):

- ☐ Parent or legal guardian must have read the PS-Pomalidomide REMS education material and agreed to ensure compliance

Checklist for female patients not of reproductive potential (natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy)

- ☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

- ☐ Possible side effects include deep vein thrombosis, pulmonary embolism, myocardial infarction, and stroke
- ☐ Not sharing pomalidomide capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood while taking pomalidomide (including dose interruptions) and for 4 weeks after stopping pomalidomide
- ☐ Not breaking, chewing, or opening pomalidomide capsules
- ☐ Instructions on pomalidomide dose and administration

Milligram (mg) Strength _____ Number of Capsules Dispensed _____

FEMALE CHILDREN (<18 YEARS OF AGE):

- ☐ Parent or legal guardian must have read the PS-Pomalidomide REMS education material and agreed to ensure compliance
- ☐ Parent or legal guardian must inform the child's healthcare provider when the child begins menses

Checklist for male patients

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

- ☐ Potential embryo-fetal toxicity and contraception (wearing a latex or synthetic condom **every time** when engaging in sexual intercourse with a female who can get pregnant, even if the patient has had a successful vasectomy, during therapy, and for 4 weeks after discontinuation of therapy)
- ☐ Female partners of males taking pomalidomide must call their healthcare provider right away if they get pregnant
- ☐ Possible side effects include deep vein thrombosis, pulmonary embolism, myocardial infarction, and stroke
- ☐ Not sharing pomalidomide capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood or sperm while taking pomalidomide (including dose interruptions) and for 4 weeks after stopping pomalidomide
- ☐ Not breaking, chewing, or opening pomalidomide capsules
- ☐ Instructions on pomalidomide dose and administration

Milligram (mg) Strength _____ Number of Capsules Dispensed _____

MALE CHILDREN (<18 YEARS OF AGE):

- ☐ Parent or legal guardian must have read the PS-Pomalidomide REMS education material and agreed to ensure compliance

All boxes and spaces must be marked or filled in during counseling with the patient for every prescription.

Counselor Signature: _____ Date: _____

For more information about pomalidomide and PS-Pomalidomide REMS, please visit www.PS-PomalidomideREMS.com, or call the REMS Call Center at **1-888-423-5436**.

Please see relevant Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS at www.PS-PomalidomideREMS.com.

The PS-Pomalidomide REMS includes both POMALYST® (pomalidomide) and generic pomalidomide products. The pomalidomide manufacturers have a contractual agreement for administration of the PS-Pomalidomide REMS. All manufacturers retain responsibility for the actions described in the REMS.

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