

((POMALYST REMS® logo))

Education and Counseling Checklist for Pharmacies

POMALYST Risk Evaluation and Mitigation Strategy (REMS) program 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 POMALYST® (pomalidomide) if pregnant or breastfeeding

- Using at the same time at least 1 highly effective method—tubal ligation, IUD, hormonal (birth controls 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

- 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 POMALYST, while taking POMALYST, during dose interruptions, and for at least 4 weeks after stopping POMALYST **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).

- 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 POMALYST 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 POMALYST capsules with anyone—especially with females who can get pregnant
- Not donating blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST
- Not breaking, chewing, or opening POMALYST capsules
- Instructions on POMALYST dose and administration

Milligram (mg) Strength _____ Number of Capsules Dispensed _____

FEMALE CHILDREN (<18 YEARS OF AGE):

- Parent or legal guardian must have read the POMALYST 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 POMALYST capsules with anyone—especially with females who can get pregnant

Not donating blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

Not breaking, chewing, or opening POMALYST capsules

Instructions on POMALYST dose and administration

Milligram (mg) Strength_____ Number of Capsules Dispensed_____

FEMALE CHILDREN (<18 YEARS OF AGE):

Parent or legal guardian must have read the POMALYST 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)

Female partners of males taking POMALYST® (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 POMALYST capsules with anyone—especially with females who can get pregnant

Not donating blood or sperm while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

Not breaking, chewing, or opening POMALYST capsules

Instructions on POMALYST dose and administration

Milligram (mg) Strength _____ Numbers of Capsules Dispensed _____

MALE CHILDREN (<18 YEARS OF AGE):

Parent or legal guardian must have read the POMALYST 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 POMALYST and the POMALYST REMS® program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation

86 Morris Ave

Summit, NJ 07901

POMALYST is only available under a restricted distribution program, POMALYST REMS®.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

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