Patient Guide to

((Pomalyst REMSTM logo))

Risk Evaluation and Mitigation Strategy (REMS)™ Program

This guide provides you important information about:

- The risks of POMALYST® (pomalidomide)
  - Birth defects (deformed babies) or death of an unborn baby
  - Blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism) can happen if you take POMALYST

- The POMALYST REMS™ Program
  - What females who can get pregnant need to know
    - Birth control options
  - What females who can not get pregnant need to know
  - What males need to know

((POMALYST logo))
Table of contents

Risks of POMALYST® (pomalidomide) ................................................................. 4

What is the POMALYST REMS™ program? ................................................. 4

What do all patients need to know about the POMALYST REMS™ program? .............. 5

What do females who can get pregnant need to know about the POMALYST REMS™ program? ........................................................................... 6

What do females who cannot get pregnant need to know about the POMALYST REMS™ program? ........................................................................ 12

What do males need to know about the POMALYST REMS™ program? ..................... 14

Mandatory confidential patient surveys .................................................................. 16

Warning to patients taking POMALYST ................................................................ 18
**Risks of POMALYST® (pomalidomide)**

POMALYST is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If POMALYST is used during pregnancy, it can cause birth defects or death to unborn babies. POMALYST must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking POMALYST.

Blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism) can happen if you take POMALYST.

**What is the POMALYST REMS™ program?**

To avoid serious risks to unborn babies, POMALYST is only available under a restricted distribution program called the "POMALYST Risk Evaluation and Mitigation Strategy (REMS)™." Only certified prescribers can prescribe POMALYST and only certified pharmacies can dispense POMALYST. In order to receive POMALYST, patients must be enrolled in the POMALYST REMS™ program and agree to follow the requirements.

For more information about POMALYST and the POMALYST REMS™ program, please visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or call the Celgene Customer Care Center toll-free at 1-888-423-5436.
What do all patients need to know about the POMALYST REMS™ program?

General guidelines

- This medicine is only for you. **Do not share it with anyone** even if they have symptoms like yours. It may harm them and can cause birth defects
- POMALYST® (pomalidomide) must be kept out of the reach of children
- Do not open or unnecessarily handle POMALYST capsules
- Keep POMALYST in a cool, dry place
- Do **not** donate blood while you are taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST
- Unused POMALYST capsules should be returned for disposal to Celgene by calling **1-888-423-5436**, or to your POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to you
What do females who can get pregnant need to know about the POMALYST REMS™ program?

A. Before taking POMALYST® (pomalidomide)

- You must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form that says you understand that POMALYST should not be used during pregnancy, and that you agree not to become pregnant while taking POMALYST.

- If there is any chance that you can get pregnant, you must agree to use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time you have sex with a male starting at least 4 weeks before taking POMALYST.

- Your healthcare provider must give you a pregnancy test 10 to 14 days before you receive your first prescription for POMALYST, and again within 24 hours before you receive your first prescription for POMALYST. If you are pregnant, you cannot take POMALYST.

- You will have pregnancy tests before starting POMALYST and while taking POMALYST, even if you agree not to have sex with a male.

- Before your healthcare provider can write your prescription for POMALYST, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies.

- Before dispensing POMALYST® (pomalidomide), your POMALYST REMS™ certified pharmacy will contact you to discuss treatment.

- Your healthcare provider will talk with you about your birth control options.
1. Choose at least 1 highly effective method and at least 1 additional effective method of birth control. Talk to your healthcare provider about the following acceptable birth control methods. See below.

**Reliable Methods of Birth Control to Use Together**

<table>
<thead>
<tr>
<th>Highly effective birth control methods</th>
<th>Additional effective birth control methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intrauterine device (IUD)</td>
<td>Male latex or synthetic condom</td>
</tr>
<tr>
<td>Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)</td>
<td>+ Diaphragm</td>
</tr>
<tr>
<td>Tubal ligation (having your tubes tied)</td>
<td>Cervical cap</td>
</tr>
<tr>
<td>Partner's vasectomy (tying of the tubes to prevent the passing of sperm)</td>
<td></td>
</tr>
</tbody>
</table>

2. Use the 2 methods of birth control at the same time

- **Remember:** You must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time you have sex with a male. However, your healthcare provider may recommend that you use 2 different methods instead for medical reasons.
What do females who can get pregnant need to know about the POMALYST REMS™ program? (continued)

- Talk to your healthcare provider to make sure that other medicines or dietary supplements you are taking do not interfere with your hormonal birth control methods
- Remember, not having sex is the only method of birth control that is 100% effective

3. Unacceptable methods of birth control

- Progesterone-only “mini-pills”
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield*

4. Take pregnancy tests

- You must have a pregnancy test performed by your healthcare provider 10 to 14 days before receiving your first prescription for POMALYST® (pomalidomide) and again within 24 hours before receiving your first prescription for POMALYST. Both pregnancy tests must have a negative result

*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.
B. While taking POMALYST® (pomalidomide)

- If you are able to get pregnant, you must continue (including during breaks [dose interruptions]) to use at the same at least 1 highly effective method and at least 1 additional effective method of birth control every time you have sex with a male.

- Remember, not having sex is the only method of birth control that is 100% effective.

- You must talk to your healthcare provider before changing any birth control methods you have already agreed to use.

- You will have a pregnancy test performed by your healthcare provider:
  - Every week during the first 4 weeks of treatment, then
  - Every 4 weeks if your menstrual cycles are regular, or
  - Every 2 weeks if your cycles are irregular
  - If you miss your period or have unusual menstrual bleeding, or
  - If your medication is not dispensed within 7 days of taking the pregnancy test.

- If you had sex with a male without using birth control, stop taking POMALYST immediately and call your healthcare provider right away.
What do females who can get pregnant need to know about the POMALYST REMS™ program?
(continued)

- If you get pregnant, or think you may be pregnant, you must immediately stop taking POMALYST® (pomalidomide). Contact your healthcare provider immediately to discuss your pregnancy. If you do not have an obstetrician, your healthcare provider will refer you to one for care and counseling. If for some reason your healthcare provider is not available, you can also call 1-888-668-2528 for information on emergency contraception.

- You must not breastfeed a baby while you are taking POMALYST.

- In order to continue receiving POMALYST, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your POMALYST REMS™ healthcare provider. To take the survey, please visit www.CelgeneRiskManagement.com, access the Celgene REMS mobile app, or call the Celgene Customer Care Center at 1-888-423-5436.

C. After you have stopped taking POMALYST® (pomalidomide)

- You must continue to use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time you have sex with a male:
  - For at least 4 weeks after stopping POMALYST, or
  - Do not have any sex with a male for 4 weeks after stopping POMALYST.

See also “General guidelines” on page 5 for requirements for all patients.
What do females who cannot get pregnant need to know about the POMALYST REMS™ program?

A. Before taking POMALYST® (pomalidomide)

- You must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form that says you are currently not pregnant and are not able to get pregnant. This means that:
  - You have been in natural menopause for at least 2 years, or
  - You have had both ovaries and/or uterus removed
- For females who have not started their period (menstruation) and are under the age of 18, a parent or legal guardian must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form that says the patient is not pregnant, is not able to get pregnant, and/or will not be having sex with a male for at least 4 weeks before starting POMALYST
- Before your healthcare provider can write your prescription for POMALYST, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies
- Before dispensing POMALYST® (pomalidomide), your POMALYST REMS™ certified pharmacy will contact you to discuss treatment

B. While taking POMALYST

- In order to continue receiving POMALYST, you must take part in a mandatory confidential survey every six months. You must also continue to discuss your treatment with your POMALYST REMS™ healthcare provider. To take the survey, please visit www.CelgeneRiskManagement.com, access the Celgene REMS mobile app, or call the Celgene Customer Care Center at 1-888-423-5436

See also “General guidelines” on page 5 for requirements for all patients.
What do males need to know about the POMALYST REMS™ program?

- You must use a latex or synthetic condom every time you have sex with a female who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)

A. Before taking POMALYST® (pomalidomide)

- You must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form. You must agree that while taking POMALYST you will use a latex or synthetic condom every time you have sex with a female who is pregnant or who is able to get pregnant
- Before dispensing POMALYST, your POMALYST REMS™ certified pharmacy will contact you to discuss treatment

B. While taking POMALYST

- You must use a latex or synthetic condom every time (including during breaks [dose interruptions]) you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- Remember, not having sex is the only method of birth control that is 100% effective
- You must tell your healthcare provider right away if you have sex with a female without using a latex or synthetic condom, or if you think for any reason that your partner is or may be pregnant. If for some reason your healthcare provider is not available, you can also call 1-888-668-2528 for information on emergency contraception
- You must not donate sperm while taking POMALYST® (pomalidomide) (including during breaks [dose interruptions])
- In order to continue receiving POMALYST, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your POMALYST REMS™ healthcare provider. To take the survey, please visit www.CelgeneRiskManagement.com, access the Celgene REMS mobile app, or call the Celgene Customer Care Center at 1-888-423-5436

C. After you have stopped taking POMALYST

- For 4 weeks after receiving your last dose of POMALYST, you must use a latex or synthetic condom every time you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- You must not donate sperm for 4 weeks after stopping POMALYST

See also “General guidelines” on page 5 for requirements for all patients.
Mandatory confidential patient surveys

As a patient who is enrolled in the POMALYST REMS™ program for POMALYST® (pomalidomide), you will need to complete a brief mandatory confidential survey as outlined below.

**Adult females who can get pregnant**
- Initial survey before first prescription
- Monthly

**Adult females who can not get pregnant**
- Initial survey before first prescription
- Every six months

**Female children**
- Initial survey before first prescription
- Monthly

**Males**
- No initial survey
- Monthly

**Mandatory confidential survey process**
- When your healthcare provider tells you to take the survey, go to the patient Mandatory Confidential Survey section of [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), the Celgene REMS mobile app, or call the Celgene Customer Care Center at **1-888-423-5436**
- Be prepared with your patient identification number
- After completing your survey, your healthcare provider will also complete a survey. Your healthcare provider will then receive authorization to write your prescription
- The prescription will be sent to a POMALYST REMS™ certified pharmacy. The POMALYST REMS™ certified pharmacy will contact you to discuss your POMALYST® (pomalidomide) therapy. You will not receive your medication until you speak with the POMALYST REMS™ certified pharmacy
Warning to patients taking POMALYST® (pomalidomide)

Attention females:

Do not take POMALYST if you are pregnant, if you are breastfeeding, or if you are able to get pregnant and are not using at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time you have sex with a male.

Attention males:

You must use a latex or synthetic condom every time you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm).

You must not donate sperm while taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST.

Attention all patients:

You must not donate blood while taking POMALYST® (pomalidomide), during breaks (dose interruptions), and for 4 weeks after stopping POMALYST.

This medicine is only for you. Do not share it with anyone even if they have symptoms like yours. It may harm them and can cause birth defects.

POMALYST must be kept out of the reach of children. Return any unused POMALYST capsules for disposal to Celgene by calling 1-888-423-5436, or to your POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to you.
For more information about POMALYST® (pomalidomide) 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, ADVERSE REACTIONS, and Medication Guide, enclosed.

POMALYST® is a registered trademark of Celgene Corporation. POMALYST REMS™ is a trademark of Celgene Corporation.

© 2015 Celgene Corporation 5/15 REMS-POM15684