



# Patient Guide to

# Pomalyst REMS<sup>®</sup>

## Risk Evaluation and Mitigation Strategy (REMS) Program

---

This guide provides you important information about:

- The risks of POMALYST<sup>®</sup> (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<sup>®</sup> 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

## Table of contents

---

Risks of POMALYST® (pomalidomide).....	3
What is the POMALYST REMS® program?.....	3
How to receive your first prescription for POMALYST.....	4
What do all patients need to know about the POMALYST REMS® program?.....	6
What do females who can get pregnant need to know about the POMALYST REMS® program? .....	7
What do females who can not get pregnant need to know about the POMALYST REMS® program? .....	14
What do males need to know about the POMALYST REMS® program? .....	16
Mandatory confidential patient surveys.....	18
Warning to patients taking POMALYST.....	20

## 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.

**This is not a comprehensive description of risks associated with the use of POMALYST. Please read the Medication Guide for POMALYST for additional information regarding risks associated with its use and see the full Prescribing Information, including Boxed Warnings, enclosed.**

## 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**.

# How to receive your first prescription for POMALYST® (pomalidomide)

## For Females:



### Counseling

Your healthcare provider will counsel you on why and how you and your partner should prevent pregnancy. Your healthcare provider will also inform you not to share the drug, not to donate blood, and about using two effective birth control methods (at least one highly effective method and one effective method) at the same time. You should be instructed not to extensively handle or open POMALYST capsules



### Pregnancy Test #1

If you can get pregnant, you must take an initial pregnancy test within 10-14 days before getting a POMALYST prescription



### Pregnancy Test #2

If you can get pregnant, you must take a second pregnancy test within 24 hours before getting a POMALYST prescription



### Enrollment

You and your healthcare provider will then complete and submit the POMALYST® (pomalidomide) Patient-Physician Agreement Form



### Complete Mandatory Confidential Survey

You and your healthcare provider will each complete a survey. Visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), access the Celgene REMS mobile app, or call **1-888-423-5436** and press 1 to take your survey



### Prescription

Your healthcare provider will send your prescription to a certified pharmacy



### Pharmacy Call

The certified pharmacy will contact you to provide counseling on the serious risks and safe-use conditions of POMALYST before you receive your prescription. They will also coordinate delivery of POMALYST to you



### Receive POMALYST

POMALYST will be shipped with a Medication Guide to the address you provide. A signature will be required to receive this shipment

For each of your following prescriptions, pregnancy tests will be required depending on your ability to get pregnant. For specific pregnancy test requirements, please refer to page 10 of this guide. For full detailed information about the POMALYST REMS® program requirements, please visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com) or review the Patient Guide to POMALYST REMS® Program.

## For Males:



### Counseling

Your healthcare provider will counsel you on why and how you and your partner should prevent pregnancy. Your healthcare provider will also inform you not to share the drug, not to donate blood or sperm, and about appropriate contraceptive use. You should be instructed not to extensively handle or open POMALYST® (pomalidomide) capsules



### Enrollment

You and your healthcare provider will then complete and submit the POMALYST® (pomalidomide) Patient-Physician Agreement Form



### Complete Mandatory Confidential Survey

You will not have to take a survey for your first prescription, but will have to for the following ones. Visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), access the Celgene REMS mobile app, or call **1-888-423-5436** and press 1 to take your survey



### Prescription

Your healthcare provider will send your prescription to a certified pharmacy



### Pharmacy Call

The certified pharmacy will contact you to provide counseling on the serious risks and safe-use conditions of POMALYST before you receive your prescription. They will also coordinate delivery of POMALYST to you



### Receive POMALYST

POMALYST will be shipped with a Medication Guide to the address you provide. A signature will be required to receive this shipment

For each of your following prescriptions, you will need to follow a similar process. For full detailed information about the POMALYST REMS® program requirements, please visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com) or review the Patient Guide to POMALYST REMS® Program.

## 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 understand and can follow information designed to prevent serious risks to unborn babies

# What do females who can get pregnant need to know about the POMALYST REMS® program? (continued)

- 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.

## Effective Methods of Birth Control Used at the Same Time

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

**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



- 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.

## What do females who can get pregnant need to know about the POMALYST REMS® program? (continued)

---

### 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 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
- **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 or if you think your birth control has failed, stop taking POMALYST® (pomalidomide) immediately and call your healthcare provider right away. Your healthcare provider will discuss your options, which may include emergency birth control. Do not wait until your next appointment to tell your healthcare provider if you miss your menstrual period or if you think you may be pregnant

- 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 your healthcare provider is not available, call the Celgene Customer Care Center at **1-888-423-5436**
- 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](http://www.CelgeneRiskManagement.com)**, access the Celgene REMS mobile app, or call the Celgene Customer Care Center at **1-888-423-5436**

---

## **Attention Females Who Can Get Pregnant:**

**Tear out this letter to take with you to your next medical appointment that discusses your birth control options.**

**This letter will help you and your healthcare provider understand what types of birth control options are the best for you.**

---

# Pomalyst REMS®

Dear Healthcare Provider,

Your patient is being treated with POMALYST® (pomalidomide). Due to its structural similarity to thalidomide, a known teratogen, POMALYST is only available under a restricted distribution program approved by the Food and Drug Administration. This program is called the POMALYST REMS® (Risk Evaluation and Mitigation Strategy) program.

## The goals of the POMALYST REMS® program are:

1. To prevent the risk of embryo-fetal exposure to POMALYST.
2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for POMALYST.

To enroll in the POMALYST REMS® program, your patient, with the knowledge of the healthcare provider who prescribed POMALYST, agreed to follow the program's contraception requirements while on POMALYST therapy. Unless she completely abstains from sexual intercourse with a male partner, she is required to use **at the same time at least one highly effective birth control method and at least one additional effective method.**

The 2 effective contraceptive methods must be started at least 4 weeks before POMALYST therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy. Please refer to the table below of the acceptable forms of contraception to help facilitate the discussion on contraception.

## Effective Methods of Birth Control Used at the Same Time

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

### Unacceptable forms of contraception:

progesterone-only "mini-pills," IUD Progesterone T, female condoms, natural family planning (rhythm method) or breastfeeding, fertility awareness, withdrawal, cervical shield (a cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception).

(continued on next page)

**Remind all patients that not having any sexual intercourse is the only birth control method that is 100% effective.**

Patients should be counseled that concomitant use of certain prescription drugs and/or dietary supplements can decrease the effects of hormonal contraception. If hormonal or IUD contraception is medically contraindicated, 2 other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after.

Instruct patient to immediately stop taking POMALYST and contact her doctor if she becomes pregnant while taking this drug, if she misses her menstrual period or experiences unusual menstrual bleeding, if she stops taking birth control or if she thinks FOR ANY REASON that she may be pregnant. Advise patient that if her doctor is not available she can call Celgene Customer Care at 1-888-423-5436.

There are other risks associated with POMALYST treatment as described in the Prescribing Information.

For full Prescribing Information, including Boxed Warnings, or details about the POMALYST REMS<sup>®</sup> program, please visit [www.pomalystrems.com](http://www.pomalystrems.com).

You may contact the Celgene REMS Department at 1-888-423-5436 if you have any questions about the information contained in this letter or the safe and effective use of POMALYST.

Sincerely,



Jay T. Backstrom, MD, MPH

Chief Medical Officer & Global Head  
Regulatory Affairs



POMALYST<sup>®</sup> and POMALYST REMS<sup>®</sup> are registered trademarks of Celgene Corporation.

### 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 6 for requirements for all patients.

## What do females who can not 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 understand and can follow information designed to prevent serious risks to unborn babies
- Before dispensing POMALYST, your POMALYST REMS® certified pharmacy will contact you to discuss treatment



## B. While taking POMALYST® (pomalidomide)

- 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 “General guidelines” on page 6 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, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- 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 had sex with a female without using a latex or synthetic condom, if you think for any reason that your partner may be pregnant, or if your partner is pregnant. If your healthcare provider is not available, call the Celgene Customer Care Center at **1-888-423-5436**
- 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 6 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**, 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<sup>®</sup> certified pharmacy. The POMALYST REMS<sup>®</sup> certified pharmacy will contact you to discuss your POMALYST<sup>®</sup> (pomalidomide) therapy. You will not receive your medication until you speak with the POMALYST REMS<sup>®</sup> certified pharmacy

For more information, contact the Celgene Customer Care Center at **1-888-423-5436**

## 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](http://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 read the Medication Guide for POMALYST for additional information regarding risks associated with its use and see the full Prescribing Information, including Boxed Warnings, enclosed.**



**Pomalyst REMS®**

**Pomalyst**  
(pomalidomide) capsules

POMALYST® and POMALYST REMS® are registered trademarks of Celgene Corporation.