



Patient Guide to the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS)

This guide provides you important information about:

The serious risks of 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)

The Pomalidomide REMS

- What females who can get pregnant need to know
 - Birth control options
 - What females who cannot get pregnant need to know
 - What males need to know
- 

Table of Contents

- 2 Risks of Pomalidomide
- 2 What is the Pomalidomide REMS?
- 3 How to Receive Your First Prescription for Pomalidomide
- 4 What Do All Patients Need to Know About the Pomalidomide REMS?
- 4 What Do Females Who Can Get Pregnant Need to Know About the Pomalidomide REMS?
- 7 What Do Females Who Cannot Get Pregnant Need to Know About the Pomalidomide REMS?
- 7 What Do Males Need to Know About the Pomalidomide REMS Program?
- 8 Mandatory Confidential Patient Surveys
- 8 Warning to Patients Taking Pomalidomide

Risks of Pomalidomide

Pomalidomide is similar to the medicine thalidomide (THALOMID®)¹. Thalidomide can cause severe life-threatening birth defects. If pomalidomide is used during pregnancy, it can cause birth defects (deformed babies) or death to unborn babies. Pomalidomide 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 pomalidomide.

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

These are not all of the serious risks of pomalidomide. Please read the Medication Guide for pomalidomide for more information about all of the risks with pomalidomide.

What is the Pomalidomide REMS?

The Pomalidomide REMS (Risk Evaluation and Mitigation Strategy) is a program to tell patients and healthcare providers about the serious risks to unborn babies with the use of pomalidomide. This program is required by the Food and Drug Administration (FDA).

Only certified prescribers can prescribe pomalidomide and only certified pharmacies can dispense pomalidomide. In order to receive pomalidomide, patients must be enrolled in the Pomalidomide REMS and agree to follow the requirements.

For more information about pomalidomide and the Pomalidomide REMS, please visit www.PomalidomideREMSProgram.com, or call the Coordinating Center toll-free at **1-866-245-7925**.

How to Receive Your First Prescription for Pomalidomide

FOR FEMALES

Counseling

Your healthcare provider will counsel you on:

- why and how you and your partner should prevent pregnancy
- using two effective birth control methods (at least one highly effective method and one effective method) at the same time
- not sharing the drug
- not donating blood
- not to open, break, chew or crush pomalidomide capsules or handle them any more than needed

Pregnancy Test #1

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

Pregnancy Test #2

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

Pregnancy Testing Schedule

- If you can get pregnant, you must take a pregnancy test weekly during the first 4 weeks of use before getting a pomalidomide prescription.
- Thereafter, pregnancy testing will need to occur every 4 weeks for female patients who can get pregnant with regular menstrual cycles and every 2 weeks for female patients who can get pregnant with irregular menstrual cycles

Enrollment

You and your healthcare provider will then complete and submit the pomalidomide ***Patient-Physician Agreement Form***

Complete Mandatory Confidential Survey

You and your healthcare provider will each complete a survey. Visit www.PomalidomideREMSProgram.com, or call **1-866-245-7925** to take your survey

Prescription

Your healthcare provider will send your prescription to a certified pharmacy

Pharmacy Call

The certified pharmacy will call you. They will provide counseling on the serious risks of pomalidomide and safety rules of the Pomalidomide REMS. They will also discuss the delivery of pomalidomide to you

Receive Pomalidomide

Pomalidomide will be shipped with a Medication Guide to the address you provide. Someone must sign for this shipment

FOR MALES

Counseling

Your healthcare provider will counsel you on:

- why and how you and your partner should prevent pregnancy
- required condom use
- not sharing the drug
- not donating blood or sperm
- not to open, break, chew or crush pomalidomide capsules or handle them any more than needed

Enrollment

You and your healthcare provider will then complete and submit the ***Patient-Physician Agreement Form***

Complete Mandatory Confidential Survey

You will not have to take a survey for your first prescription. You will have to take a survey for the following ones. Visit www.PomalidomideREMSProgram.com, or call **1-866-245-7925** to take your survey

Prescription

Your healthcare provider will send your prescription to a certified pharmacy

Pharmacy Call

The certified pharmacy will call you. They will provide counseling on the serious risks of pomalidomide and safety rules of the Pomalidomide REMS. They will also discuss the delivery of pomalidomide to you

Receive Pomalidomide

Pomalidomide will be shipped with a Medication Guide to the address you provide. Someone must sign for this shipment

For each of your following prescriptions, you will need to follow a similar process. For more information about the Pomalidomide REMS requirements, please visit www.PomalidomideREMSProgram.com.

For each of your following prescriptions, pregnancy tests will be required if you are able to get pregnant. For pregnancy test requirements, please refer to this guide. For more information about the Pomalidomide REMS requirements, please visit www.PomalidomideREMSProgram.com.

What Do All Patients Need to Know About the Pomalidomide REMS?

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
- Pomalidomide must be kept out of the reach of children
- Do not open or unnecessarily handle pomalidomide capsules
- Keep pomalidomide in a cool, dry place
- Do **not** donate blood while you are taking pomalidomide, during breaks (dose interruptions), and for 4 weeks after stopping pomalidomide. Return unused pomalidomide to the Pomalidomide REMS, your prescriber, or the pharmacy that dispensed your pomalidomide

What Do Females Who Can Get Pregnant Need to Know About the Pomalidomide REMS?

Before Taking Pomalidomide

- You must sign the **Patient-Physician Agreement Form**. This form says you understand that pomalidomide should not be used during pregnancy, and that you agree not to become pregnant while taking pomalidomide
- 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 pomalidomide
- Your healthcare provider must give you a pregnancy test 10 to 14 days before you receive your first prescription for pomalidomide, and again within 24 hours before you receive your first prescription for pomalidomide. If you are pregnant, you cannot take pomalidomide
- You will have pregnancy tests before starting pomalidomide and while taking pomalidomide, even if you agree not to have sex with a male
 - Following your first prescription, you will need to adhere to the following pregnancy testing schedule:
 - Weekly during the first 4 weeks of use
 - Thereafter, pregnancy testing will occur every 4 weeks for female patients who can get pregnant with regular menstrual cycles and every 2 weeks for female patients who can get pregnant with irregular menstrual cycles
- Before your healthcare provider can write your prescription for pomalidomide, you must take part in a mandatory confidential survey. The survey will make sure that you understand and can follow the safety rules to prevent serious risks to unborn babies
- Before shipping the drug, your Pomalidomide 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)	Male latex or synthetic condom
Hormonal methods (birth control pills, hormonal patches, injections, vaginal ring, or implants)	Diaphragm
Tubal ligation (having your tubes tied)	Cervical cap
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	

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 be given a pregnancy test by your healthcare provider 10 to 14 days before receiving your first prescription for pomalidomide. You must be given another pregnancy test within 24 hours before receiving your first prescription for pomalidomide. Both pregnancy tests must be negative

*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

While Taking 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 or if you think your birth control has failed, stop taking 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 pomalidomide. Contact your healthcare provider immediately to discuss your pregnancy. If you do not have an obstetrician (OB/GYN), your healthcare provider will refer you to one for care and counseling. If your healthcare provider is not available, call the Coordinating Center at **1-866-245-7925**
- You must not breastfeed a baby while you are taking pomalidomide
- In order to continue receiving pomalidomide, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your Pomalidomide REMS healthcare provider. To take the survey, please visit www.PomalidomideREMSProgram.com, or call the REMS Coordinating Center at **1-866-245-7925**

After You Have Stopped Taking 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 pomalidomide, or
 - Do not have any sex with a male for 4 weeks after stopping pomalidomide

POMALIDOMIDE REMS

Patient Guide GYN Letter

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.

Dear Healthcare Provider,

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

The goals of the Pomalidomide REMS are:

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

To enroll in the Pomalidomide REMS, your patient, with the knowledge of the healthcare provider who prescribed pomalidomide, agreed to follow the program's contraception requirements while on pomalidomide 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 two effective contraceptive methods must be started at least 4 weeks before pomalidomide 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 ring, or implants) Tubal ligation (having your tubes tied) Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	Male latex or synthetic condom Diaphragm 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).

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, two other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after. Instruct patient to immediately stop taking pomalidomide 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 the REMS Coordinating Center at **1-866-245-7925**.

There are other risks associated with pomalidomide treatment as described in the Prescribing Information. For Prescriber Information, including Boxed Warnings, or details about the Pomalidomide REMS, please visit www.PomalidomideREMSProgram.com. You may contact the REMS Coordinating Center at **1-866-245-7925** if you have any questions about the information contained in this letter or the safe and effective use of pomalidomide.

Sincerely,
Pomalidomide REMS Applicants

What Do Females Who Cannot Get Pregnant Need to Know About the Pomalidomide REMS?

Before Taking Pomalidomide

- You must sign the ***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 ***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 pomalidomide
- Before your healthcare provider can write your prescription for pomalidomide, you must take a mandatory confidential survey. The survey will make sure that you understand and can follow safety rules to prevent serious risks to unborn babies
- Before dispensing pomalidomide, your Pomalidomide REMS certified pharmacy will call you to discuss treatment

While Taking Pomalidomide

- In order to continue receiving pomalidomide, you must take part in a mandatory confidential survey every six months. You must also continue to discuss your treatment with your Pomalidomide REMS healthcare provider. To take the survey, please visit www.PomalidomideREMSProgram.com, or call the REMS Coordinating Center at **1- 866-245-7925**

What Do Males Need to Know About the Pomalidomide REMS?

- 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)

Before Taking Pomalidomide

- You must sign the ***Patient-Physician Agreement Form***. You must agree that while taking pomalidomide 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 pomalidomide, your Pomalidomide REMS certified pharmacy will call you to discuss treatment

While Taking Pomalidomide

- 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, or 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 REMS Coordinating Center at **1-866-245-7925**
- You must **not** donate sperm while taking pomalidomide (including during breaks [dose interruptions])
- In order to continue receiving pomalidomide, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your Pomalidomide REMS healthcare provider. To take the survey, please visit www.PomalidomideREMSProgram.com, or call the REMS Coordinating Center at **1-866-245-7925**

After You Have Stopped Taking Pomalidomide

- For 4 weeks after receiving your last dose of pomalidomide, 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 pomalidomide
- See also “General guidelines” on page 4 for requirements for all patients

Mandatory Confidential Patient Surveys

As a patient who is enrolled in the Pomalidomide REMS for pomalidomide, you must complete a brief mandatory confidential survey as outlined below.

Adult females who can get pregnant

- Initial survey before first prescription
- Monthly

Female child who can get pregnant

- Initial survey before first prescription
- Monthly

Male child

- No initial survey
- Monthly

Adult females who cannot get pregnant

- Initial survey before first prescription
- Every six months

Female child who cannot get pregnant

- Initial survey before first prescription
- Monthly

Adult 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.PomalidomideREMSProgram.com, or call the REMS Coordinating Center at **1-866-245-7925**
- 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 Pomalidomide REMS certified pharmacy. The Pomalidomide REMS certified pharmacy will call you to discuss your pomalidomide therapy. You will not receive your medication until you speak with the Pomalidomide REMS certified pharmacy
- For more information, contact the REMS Coordinating Center at **1-866-245-7925**

Warning to Patients Taking Pomalidomide

Attention Females:

Do **not** take pomalidomide 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 pomalidomide, during breaks (dose interruptions), and for 4 weeks after stopping pomalidomide.

Attention All Patients:

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

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.

Pomalidomide must be kept out of the reach of children. Return unused pomalidomide to the Pomalidomide REMS, your prescriber, or the pharmacy that dispensed your pomalidomide.

For more information about pomalidomide and the Pomalidomide REMS, please visit www.PomalidomideREMSProgram.com, or call the Coordinating Center at **1-866-245-7925**.

Pomalidomide is only available under a restricted distribution program, Pomalidomide REMS.

Please read the Medication Guide for pomalidomide for more information about risks with pomalidomide