

# Risk Evaluation and Mitigation Strategy (REMS) Document

## Pomalidomide REMS Program

### I. ADMINISTRATIVE INFORMATION

Initial Shared System REMS Approval: 10/2020

### II. REMS GOALS

The goals of the Pomalidomide REMS are as follows:

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.

### III. REMS REQUIREMENTS

The Pomalidomide Applicants must ensure that healthcare providers, patients, pharmacies, and wholesalers-distributors comply with the following requirements:

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1. Healthcare providers who prescribe pomalidomide must:	
To become certified to prescribe	<ol style="list-style-type: none"><li>1. Review the drug's Prescribing Information.</li><li>2. Enroll into the Pomalidomide REMS by completing the <a href="#">Prescriber Enrollment Form</a> and submitting it to the Pomalidomide REMS.</li><li>3. Review the following: <a href="#">Welcome Letter</a>, <a href="#">Prescriber Guide</a>, and <a href="#">REMS Education and Prescribing Safety Kit</a>.</li></ol>
Before treatment initiation (first prescription); within 10-14 days and again within 24 hours	<ol style="list-style-type: none"><li>4. For females (adults and children) who can get pregnant: Assess the patient's pregnancy status by ordering and confirming a negative test result. Document and submit the results to the REMS program.</li></ol>
Before treatment initiation (first prescription)	<ol style="list-style-type: none"><li>5. For all patients: Counsel the patient on the benefits and risks of pomalidomide therapy, including risks described in the Boxed WARNINGS and the need to complete mandatory patient surveys with the Pomalidomide REMS using the <a href="#">Patient Guide</a> and <a href="#">Patient-Physician Agreement Form</a>. Provide a copy of the materials to the patient.</li><li>6. For females (adults and children) who can get pregnant: Counsel the patient on contraception requirements and emergency contraception using the <a href="#">Patient Guide</a> and the <a href="#">Emergency Contraception Brochure</a>. Provide a copy of the materials to the patient.</li></ol>

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	<p>7. For males (adults and children): Counsel the patient on the barrier contraception requirements and emergency contraception using the <a href="#">Patient Guide</a> and the <a href="#">Emergency Contraception Brochure</a>. Provide a copy of the materials to the patient.</p> <p>8. Enroll the patient by completing and submitting the <a href="#">Patient-Physician Agreement Form for Female Child Who Can Get Pregnant</a>, <a href="#">Patient-Physician Agreement Form for Female Child Who Cannot Get Pregnant</a>, <a href="#">Patient-Physician Agreement Form for Male Child</a>, <a href="#">Patient-Physician Agreement Form for Adult Female Who Can Get Pregnant</a>, <a href="#">Patient-Physician Agreement Form for Adult Female Who Cannot Get Pregnant</a>, or <a href="#">Patient-Physician Agreement Form for Adult Male</a> to the Pomalidomide REMS.</p> <p>9. Obtain authorization by contacting the REMS program to complete the prescriber survey to verify the patient's reproductive status, negative pregnancy test status, and completion of counseling. Document the prescription authorization number and the patient's risk category on the prescription.</p> <p>10. Prescribe no more than a 28 days' supply.</p> <p>11. Not prescribe refills or prescribe over the phone.</p>
During treatment; weekly for at least the first 4 weeks	12. For females (adults and children) who can get pregnant: Assess the patient's pregnancy status by ordering and reviewing the results of her pregnancy test.
During treatment; every 2 weeks after the first 4 weeks	13. For females (adults and children) with irregular menstrual cycles who can get pregnant: Assess the patient's pregnancy status by ordering and reviewing the results of her pregnancy test.
During treatment; every 4 weeks after the first 4 weeks	14. For females (adults and children) with regular menstrual cycles who can get pregnant: Assess the patient's pregnancy status by ordering and reviewing the results of her pregnancy test. Document and submit the results to the REMS program.
During treatment: before each prescription	<p>15. For all patients: Counsel the patient on the need to complete the patient survey.</p> <p>16. For females (adults and children) who can get pregnant: Counsel the patient on contraception requirements and emergency contraception using the <a href="#">Patient Guide</a> and the <a href="#">Emergency Contraception Brochure</a>.</p> <p>17. For males (adults and children): Counsel the patient on the barrier contraception requirements using the <a href="#">Patient Guide</a>.</p> <p>18. Obtain authorization by contacting the REMS program to complete the prescriber survey to verify the patient's reproductive status, negative pregnancy test status, and</p>

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completion of counseling. Document the prescription authorization number and the patient's risk category on the prescription.

- 19. Prescribe no more than a 28 days' supply.
- 20. Not prescribe refills or prescribe over the phone.

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At all times

- 21. Report any pregnancies in female patients or female partners of male patients immediately to the Pomalidomide REMS.
- 22. Return all unused product from patients to the Pomalidomide REMS.

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**2. Females (adults and children) who can get pregnant who are prescribed pomalidomide:**

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Before treatment initiation; 4 weeks

- 1. Adhere to the safe use conditions: using contraception and not getting pregnant as described in the [Patient Guide](#) and the [Patient-Physician Agreement Form](#).

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Before treatment initiation; within 10-14 days and again within 24 hours

- 2. Get a pregnancy test as directed by your prescriber.

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Before treatment initiation

- 3. Receive counseling from the prescriber on the benefits and risks of pomalidomide therapy and the need to complete the patient survey, on contraception requirements and emergency contraception.
  - 4. Review the [Patient Guide](#) and the [Emergency Contraception Brochure](#).
  - 5. Enroll into the Pomalidomide REMS by completing the [Patient-Physician Agreement Form for Adult Female Who Can Get Pregnant](#) or [Patient-Physician Agreement Form for Female Child Who Can Get Pregnant](#) with the prescriber. Enrollment information will be provided to the Pomalidomide REMS.
  - 6. Complete the patient survey.
  - 7. Receive counseling from the pharmacy on the benefits and risks of pomalidomide; not sharing pomalidomide; not donating blood; not breaking, chewing, or opening pomalidomide capsules; instructions on dose and administration; reading the Pomalidomide REMS education materials; and being compliant with the REMS requirements.
  - 8. Receive counseling from the pharmacy on the embryo-fetal toxicity with exposure to pomalidomide; contraception requirements; pregnancy testing requirement; not taking pomalidomide if pregnant, breastfeeding, and not using contraception; and to immediately stop taking pomalidomide and notify the prescriber if pregnant or suspect you may be pregnant.
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During treatment; weekly for at least the first 4 weeks	9. Get a pregnancy test as directed by your prescriber.
During treatment; before each prescription	<p>10. Receive counseling from the prescriber on contraception requirements and emergency contraception and the need to complete the patient survey.</p> <p>11. Get a pregnancy test as directed by your prescriber.</p> <p>12. Receive counseling from the pharmacy on the benefits and risks of pomalidomide, not sharing pomalidomide, not donating blood, not breaking, chewing, or opening pomalidomide capsules, instructions on dose and administration, reading the Pomalidomide REMS education materials, and being compliant with the REMS requirements.</p> <p>13. Receive counseling from the pharmacy on embryo-fetal toxicity with exposure to pomalidomide; contraception requirements; pregnancy testing requirements; not taking pomalidomide if pregnant, breastfeeding or not using contraception; and to immediately stop taking pomalidomide and notify the prescriber if pregnant or suspect you may be pregnant.</p> <p>14. Complete patient survey.</p>
During treatment and after treatment discontinuation; for 4 weeks	<p>15. Adhere to the safe-use conditions: Not donating blood.</p> <p>16. Adhere to the safe-use conditions: Using contraception as described in the <a href="#">Patient Guide</a> and the <a href="#">Patient-Physician Agreement Form</a>, not taking pomalidomide if pregnant, breastfeeding, or not using contraception; not getting pregnant.</p>
At all times	<p>17. Inform the prescriber if pregnant, miss a menstrual period, experience unusual menstrual bleeding, stop using contraception, or think for any reason that you may be pregnant. Stop taking pomalidomide immediately.</p> <p>18. Return unused pomalidomide to the Pomalidomide REMS, your prescriber, or the pharmacy that dispensed the pomalidomide.</p> <p>19. Adhere to safe-use conditions: Not sharing pomalidomide, not breaking, chewing, or opening pomalidomide capsules, and keeping pomalidomide out of reach of children.</p>

### 3. Adult females who cannot get pregnant who are prescribed pomalidomide:

Before treatment initiation	<p>1. Receive counseling from the prescriber on the benefits and risks of pomalidomide and the need to complete the patient survey.</p> <p>2. Review the <a href="#">Patient Guide</a>.</p> <p>3. Complete patient survey.</p> <p>4. Enroll into the Pomalidomide REMS by completing a <a href="#">Patient-Physician Agreement Form for Adult Female Who Cannot Get</a></p>
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	<p><a href="#">Pregnant</a> with the prescriber. Enrollment information will be provided to the Pomalidomide REMS.</p> <p>5. Receive counseling from the pharmacy on the benefits and risks of pomalidomide therapy; not sharing pomalidomide, not donating blood; not breaking, chewing, or opening pomalidomide capsules; instructions on dose and administration; reading the Pomalidomide REMS education materials; and being compliant with the REMS requirements.</p>
During treatment; before each prescription	6. Receive counseling from the pharmacy on the benefits and risks of pomalidomide therapy; not sharing pomalidomide; not donating blood; not breaking, chewing, or opening pomalidomide capsules; instructions on dose and administration; reading the Pomalidomide REMS education materials; and being compliant with the REMS requirements.
During treatment; every 6 months	<p>7. Receive counseling from the prescriber on the need to complete the patient survey.</p> <p>8. Complete the patient survey.</p>
During treatment and after treatment discontinuation; for 4 weeks	9. Adhere to the safe-use conditions: Not donating blood.
At all times	<p>10. Return unused pomalidomide to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide.</p> <p>11. Adhere to the safe-use conditions: Not sharing pomalidomide; not breaking, chewing, or opening pomalidomide capsules; and keeping pomalidomide out of reach of children.</p>

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**4. Female children who cannot get pregnant and who are prescribed pomalidomide:**

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Before treatment initiation	<p>1. Receive counseling from the prescriber on the benefits and risks of pomalidomide and the prescriber need to complete the patient survey.</p> <p>2. Review the <a href="#">Patient Guide</a>.</p> <p>3. Enroll into the Pomalidomide REMS by completing, the <a href="#">Patient-Physician Agreement Form for Female Child Who Cannot Get Pregnant</a> with the prescriber. Enrollment information will be provided to the Pomalidomide REMS.</p> <p>4. Complete the patient survey.</p> <p>5. Receive counseling from the pharmacy on the benefits and risks of pomalidomide; not sharing pomalidomide, not donating blood; not breaking, chewing, or opening pomalidomide capsules; instructions on dose and administration; reading the Pomalidomide REMS education materials; and being compliant with the REMS requirements.</p>
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	6. Receive counseling from the pharmacy to inform their pomalidomide prescriber when the patient begins menses.
During treatment; before each prescription	<p>7. Receive counseling from the prescriber on the need to complete the patient survey.</p> <p>8. Receive counseling from the pharmacy on the benefits and risks of pomalidomide, not sharing pomalidomide; not donating blood; not breaking, chewing, or opening pomalidomide capsules; instructions on dose and administration; reading the Pomalidomide REMS education materials; and being compliant with the REMS requirements.</p> <p>9. Receive counseling from the pharmacy to inform their pomalidomide prescriber when the patient begins menses.</p> <p>10. Complete the patient survey.</p>
During treatment and after treatment discontinuation; for 4 weeks	11. Adhere to the safe-use conditions: not donating blood.
At all times	<p>12. Inform the prescriber when the patient begins menses.</p> <p>13. Return unused pomalidomide to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide.</p> <p>14. Adhere to safe-use conditions: Not sharing pomalidomide; not breaking, chewing, or opening pomalidomide capsules; and keeping pomalidomide out of reach of children.</p>

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**5. Males (adults and children) who are prescribed pomalidomide:**

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Before treatment initiation	<p>1. Receive counseling from the prescriber on the benefits and risks of pomalidomide, the need to complete the patient survey, barrier contraception requirements, and emergency contraception.</p> <p>2. Review the <a href="#">Patient Guide</a> and the <a href="#">Emergency Contraception Brochure</a>.</p> <p>3. Enroll into the Pomalidomide REMS by completing a <a href="#">Patient-Physician Agreement Form for Adult Male</a> or <a href="#">Patient-Physician Agreement Form for Male Child</a> with the prescriber. Enrollment information will be provided to the Pomalidomide REMS.</p> <p>4. Receive counseling from the pharmacy on the benefits and risks of pomalidomide; not sharing pomalidomide; not donating blood; not breaking, chewing, or opening pomalidomide capsules; instructions on dose and administration; reading the Pomalidomide REMS education materials; and being compliant with the REMS requirements.</p> <p>5. Receive counseling from the pharmacy on embryo-fetal toxicity with exposure to pomalidomide, barrier contraception requirements, and not donating sperm.</p>
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During treatment; before each prescription	<ol style="list-style-type: none"> <li>6. Receive counseling from the prescriber on barrier contraception requirements and emergency contraception, and the need to complete the patient survey.</li> <li>7. Receive counseling from the pharmacy on the benefits and risks of pomalidomide; not sharing pomalidomide; not donating blood; not breaking, chewing, or opening pomalidomide capsules; instructions on dose and administration; reading the Pomalidomide REMS education materials; and being compliant with the REMS requirements.</li> <li>8. Receive counseling from the pharmacy on the embryo-fetal toxicity with exposure to pomalidomide, barrier contraception requirements, and not donating sperm.</li> <li>9. Complete the patient survey.</li> </ol>
During treatment and after treatment discontinuation; for 4 weeks	<ol style="list-style-type: none"> <li>10. Adhere to the safe-use conditions: Using barrier contraception as described in the <a href="#">Patient Guide</a> and <a href="#">Patient-Physician Agreement Form</a>.</li> <li>11. Adhere to the safe-use conditions: Not donating blood or sperm.</li> </ol>
At all times	<ol style="list-style-type: none"> <li>12. Inform the prescriber about unprotected sexual contact with a female who can become pregnant, or about a sexual partner who might be pregnant.</li> <li>13. Return unused pomalidomide to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide.</li> <li>14. Adhere to safe-use conditions: Not sharing pomalidomide; not breaking, chewing, or opening pomalidomide capsules; and keeping pomalidomide out of reach of children.</li> </ol>

**6. Pharmacies that dispense pomalidomide:**

To become certified to dispense	<ol style="list-style-type: none"> <li>1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS program on behalf of the Pharmacy.</li> <li>2. Have the authorized representative review the following: <a href="#">Pharmacy Guide</a>, <a href="#">Pharmacy Training</a>, <a href="#">Prescribing Information</a>.</li> <li>3. Have the authorized representative enroll in the Pomalidomide REMS by completing the <a href="#">Pharmacy Enrollment Form</a> and submitting it to the Pomalidomide REMS.</li> <li>4. Have the authorized representative complete the <a href="#">Pharmacy Certification Quiz</a> and submit it to the REMS program.</li> <li>5. Train all relevant staff involved in counseling and dispensing pomalidomide on the Pomalidomide REMS requirements using the REMS <a href="#">Pharmacy Training</a>.</li> </ol>
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6. Establish processes and procedures to identify new staff involved in counseling and dispensing pomalidomide and ensure they are trained.
  7. Establish processes and procedures to verify there are 7 days or less remaining on the patient's existing prescription, no more than 28 days' supply is dispensed, and the prescriber provided the authorization number and patient risk category on the prescription.
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Before dispensing

8. For all patients: Counsel the patient on the benefits and risks of pomalidomide, and safe-use requirements using the [Education and Counseling Checklist for Pharmacies](#).
  9. For females (adult and children) who can get pregnant, counsel on the embryo-fetal toxicity with exposure to pomalidomide and her safe-use conditions using the [Education and Counseling Checklist for Pharmacies](#).
  10. For female children who cannot get pregnant: Counsel the patient to inform the prescriber when menses begins using the [Education and Counseling Checklist for Pharmacies](#).
  11. For males (adult and children): Counsel the patient on the embryo-fetal toxicity with exposure to pomalidomide and additional safe-use requirements using the [Education and Counseling Checklist for Pharmacies](#).
  12. Verify that a prescription authorization number and patient risk category are documented on each prescription through the processes and procedures established as a requirement of the REMS program.
  13. Obtain a confirmation number to dispense each prescription by contacting the REMS program to verify the prescriber is certified, the patient is enrolled and is not pregnant, and the authorization number is valid.
  14. Document the confirmation number and the date it was obtained on the prescription.
  15. Complete the [Education and Counseling Checklist for Pharmacies](#). Retain a completed copy in the patient's record.
  16. Dispense no more than a 28 days' supply.
  17. Dispense only if there are 7 days or less remaining on the existing prescription.
  18. Do not accept verbal prescription orders over the phone.
  19. Do not dispense refills.
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After dispensing	<p>20. Ship dispensed product within 24 hours of receiving the confirmation number or it must be picked up within 24 hours of obtaining the confirmation number.</p> <p>21. For females (adult and children) who can get pregnant ship pomalidomide the same day the confirmation number is obtained or it must be picked up within 24 hours of obtaining the confirmation number.</p>
To maintain certification to dispense	<p>22. Have any new authorized representative enroll in the Pomalidomide REMS by successfully completing the <a href="#">Pharmacy Certification Quiz</a> and <a href="#">Pharmacy Enrollment Form</a> and submitting both to the Pomalidomide REMS.</p>
At all times	<p>23. Report pregnancies immediately to the Pomalidomide REMS.</p> <p>24. Do not distribute, transfer, loan, or sell pomalidomide, except with the permission of the Pomalidomide REMS.</p> <p>25. Maintain records of each prescription dispensed with the corresponding confirmation number, date it was obtained, and completed <a href="#">Education and Counseling Checklist for Pharmacies</a>.</p> <p>26. Comply with audits carried out by the Pomalidomide REMS to ensure that all processes and procedures are in place and are being followed.</p> <p>27. Accept unused product from the patient or the prescriber.</p> <p>28. Return unused product from the patient or the prescriber to the Pomalidomide REMS.</p>
<b>7. Wholesalers-distributors that distribute pomalidomide:</b>	
To be able to distribute	<p>1. Establish processes and procedures to ensure that the drug is distributed only to certified pharmacies.</p> <p>2. Train all relevant staff involved in distributing on the REMS program requirements.</p>
At all times	<p>3. Distribute only to certified pharmacies.</p> <p>4. Maintain records of distributions.</p> <p>5. Comply with audits carried out by the Pomalidomide REMS to ensure that all processes and procedures are in place and are being followed.</p>

**Pomalidomide Applicants must provide training to healthcare providers who prescribe pomalidomide.**

The training must include the following educational materials: [Welcome Letter](#), [Prescriber Guide](#), and [REMS Education and Prescribing Safety Kit](#). The training must be available online and hardcopy format via mail.

**Pomalidomide Applicants must provide training to pharmacies that dispense pomalidomide.**

The training includes the following educational material(s): [Pharmacy Guide](#), [Education and Counseling Checklist for Pharmacies](#), [Pharmacy Training](#), [Pharmacy Certification Quiz](#). The training must be available online and hardcopy format via mail.

**To support REMS program operations, Pomalidomide Applicants must:**

1. Establish and maintain the [REMS program website](#), [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com). The [REMS program website](#) must include the capability to complete prescriber certification online, to enroll and to take REMS surveys online, and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the [REMS program website](#). The [REMS program website](#) must not link back to the promotional product website(s).
2. Make the [REMS program website](#) fully operational and all REMS materials available through [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com), or by calling the Pomalidomide REMS within 90 days of when the first abbreviated new drug application (ANDA) referencing POMALYST® (pomalidomide) is approved.
3. Establish and maintain a REMS program Call Center for REMS participants at 1-866-245-7925.
4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the Pomalidomide REMS.
5. Ensure prescribers are able to enroll into the Pomalidomide REMS by mail, phone, fax, and online.
6. Ensure prescribers are able to enroll their patients into the Pomalidomide REMS by mail, fax, and online.
7. Ensure prescribers are able to complete prescriber surveys by phone and online.
8. Ensure prescribers are able to obtain an authorization number by phone and online. For females who can get pregnant, the authorization is valid for 7 days from the date of the last pregnancy test. For all other patients, the authorization number is valid for 30 days from the date the authorization number is issued.
9. Ensure patients are able to take patient surveys by phone and online.
10. Ensure pharmacies are able to obtain dispense confirmation numbers by phone or online.
11. Ensure prescribers, patients, and pharmacists are able to report pregnancies by phone, mail, and fax.
12. Provide [Prescriber Enrollment Form](#), [Prescriber Guide](#), and the Prescribing Information to Pomalidomide REMS participants who (1) attempt to prescribe pomalidomide and are not yet certified or (2) inquire about how to become certified.
13. Notify prescribers within 24 hours after they become certified in the Pomalidomide REMS.
14. Notify prescribers when patient enrollment is confirmed by fax and online.
15. Provide certified prescribers access to the database of their enrolled patients and certified pharmacies.

16. Provide certified pharmacies access to the REMS system to participate in the Pomalidomide REMS.
17. Establish and maintain a registry which includes a reporting and collection system registry for female patients or female partners of male patients receiving pomalidomide to provide information on pregnancy outcomes and root cause of pregnancy.
18. Ensure that once a report of a pregnancy is received, the Pomalidomide REMS follows up to obtain all required data for the registry.

**To ensure REMS participants' compliance with the REMS program, Pomalidomide Applicants must:**

19. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: pomalidomide prescribing and dispensing; enrollment and certification of prescribers and pharmacies; enrollment, appropriate risk categorization, and pregnancy testing results of patients; and audits of Pomalidomide REMS pharmacies. These records must be readily available for FDA inspections.
20. Establish a plan for addressing noncompliance with REMS program requirements.
21. Ensure patients who discontinue treatment for 12 consecutive months must re-enroll in the REMS.
22. Monitor prescribers, pharmacies, and patients on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if noncompliance is identified, including de-certification.
23. Monitor and ensure that patients have been assigned correctly to one of the following patient risk categories. Confirm risk category during the patient enrollment process:
  - Adult female who can get pregnant: all females who are menstruating, amenorrheic from previous medical treatments, under 50 years, and/or perimenopausal.
  - Female child who can get pregnant: all females under 18 years who are menstruating.
  - Adult female who cannot get pregnant: females who have had a natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy.
  - Female child who cannot get pregnant: all females under 18 years who are not menstruating and do not show signs of puberty.
  - Adult male: 18 years or older.
  - Male child: under 18 years.
24. Audit all certified pharmacies within 90 calendar days of certification to ensure that all the processes and procedures are in place and functioning to comply with the Pomalidomide REMS requirements, annually for the first 2 years, and once every 3 years thereafter.
25. Audit wholesaler-distributors no later than 90 calendar days after they become authorized to distribute the drug to ensure that all REMS processes and procedures are in place, functioning and support the REMS requirements.
26. Take reasonable steps to improve implementation of and compliance with the requirements in the Pomalidomide REMS Program based on monitoring and evaluation of the Pomalidomide REMS Program.

#### **IV. REMS MATERIALS**

The following materials are part of the Pomalidomide REMS:

**Enrollment Forms:**

Prescriber:

1. [Prescriber Enrollment Form](#)

Pharmacy:

2. [Pharmacy Enrollment Form](#)

Patient:

3. [Patient-Physician Agreement Form for Adult Female Who Can Get Pregnant](#)
4. [Patient-Physician Agreement Form for Female Child Who Can Get Pregnant](#)
5. [Patient-Physician Agreement Form for Adult Female Who Cannot Get Pregnant](#)
6. [Patient-Physician Agreement Form for Female Child Who Cannot Get Pregnant](#)
7. [Patient-Physician Agreement Form for Adult Male](#)
8. [Patient-Physician Agreement Form for Male Child](#)

**Training and Educational Materials:**

Prescriber:

9. [Welcome Letter](#)
10. [Prescriber Guide](#)
11. [REMS Education and Prescribing Safety Kit](#)

Pharmacy:

12. [Pharmacy Guide](#)
13. [Pharmacy Training](#)
14. [Pharmacy Certification Quiz](#)

Patient:

15. [Patient Guide](#)
16. [Emergency Contraception Brochure](#)
17. [Patient Resource Pack Envelope](#)

**Patient Care Forms:**

18. [Education and Counseling Checklist for Pharmacies](#)

**Other Materials:**

19. [REMS Program Website](#)

## Prescriber Enrollment Form

### Instructions:

All prescribers **must** be certified to prescribe pomalidomide. To become certified:

- Enroll online at [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) for real time processing.
- Or fax both pages to the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS) at 1-844-872-5446

You will receive confirmation of your certification via e-mail.

Pomalidomide is contraindicated in pregnant females and females capable of becoming pregnant. Females who can get pregnant may be treated with pomalidomide provided adequate precautions are taken to avoid pregnancy. Pomalidomide is available only through a restricted distribution program called the Pomalidomide REMS.

The REMS Coordinating Center is available to answer questions regarding this program and initiating treatment with pomalidomide. Please call **1-866-245-7925** for assistance.

By completing, signing, and submitting this form, I acknowledge that I have reviewed the Prescribing Information for pomalidomide, and I agree to be enrolled in the Pomalidomide REMS.

### When prescribing pomalidomide, I agree to:

1. Provide patient counseling on the benefits and risks of pomalidomide therapy, including Boxed Warnings and the need to **complete mandatory** patient surveys with the Pomalidomide REMS using the information in the Medication Guide, the **Patient Guide** and the **Patient-Physician Agreement Form**.
2. Provide each patient with a copy of the **Patient Guide** and the **Patient-Physician Agreement Form**.
3. Enroll the patient by completing the appropriate **Patient-Physician Agreement Form** for each new patient.
4. Provide scheduled pregnancy testing for females who can get pregnant and verify negative pregnancy test results prior to writing a new prescription or subsequent prescription.
5. Provide contraception and emergency contraception counseling with each new prescription prior to and during pomalidomide treatment.
6. Obtain authorization by contacting the Pomalidomide REMS to complete the prescriber survey to verify the patient's reproductive status, negative pregnancy test status, and completion of counseling. Document the prescription authorization number and the patient's risk category on the prescription.
7. Facilitate patient compliance with an initial mandatory confidential patient survey (online or by telephone interview).
8. Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions.
9. Submit the prescription to a pharmacy certified by the Pomalidomide REMS for dispensing.
10. Report any pregnancies in female patients or female partners of male patients prescribed pomalidomide immediately to the Pomalidomide REMS.
11. Remind patients to return unused pomalidomide to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide.
12. Return all unused product from patients to the Pomalidomide REMS.
13. Re-enroll patients in the Pomalidomide REMS if pomalidomide therapy is required and previous therapy with pomalidomide has been discontinued for 12 consecutive months.

**I understand that if I do not maintain compliance with the requirements of the Pomalidomide REMS, I will no longer be able to prescribe pomalidomide.**

**PRESCRIBER INFORMATION** Note: Fields marked with an \* are REQUIRED.

* Prescriber First Name:		*Last Name:	
*Prescriber National Provider Identifier (NPI)#:			
Institution Name (if applicable):			
*Prescriber Street Address:			
*City:		*State:	*ZIP Code:
*Telephone Number:		Alternative Telephone Number:	
*Office Fax Number:		*Email:	
Prescriber Degree: <input type="checkbox"/> MD <input type="checkbox"/> DO <input type="checkbox"/> NP <input type="checkbox"/> PA <input type="checkbox"/> Other			

**OFFICE CONTACT (PRIMARY)**

First Name:	Last Name:	Telephone Number:
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**OFFICE CONTACT (SECONDARY)**

First Name:	Last Name:	Telephone Number:
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 *Prescriber Signature:	*Date: Month/Day/Year
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By completing, signing, and submitting this form and receiving certification confirmation by e-mail, you will be certified in the Pomalidomide REMS and may begin prescribing pomalidomide. You only need to enroll and complete the certification in the program once, and you are under no obligation to prescribe pomalidomide.

**To report adverse events, please contact the REMS Coordinating Center at 1-866-245-7925**

You may also report to the FDA via <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>,  
phone: 1-800-FDA-1088, Fax: 1-800-FDA-0178 or mail MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

**POMALIDOMIDE REMS**

Phone: 1-866-245-7925

[www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com)

Fax: 1-844-872-5446

## Pharmacy Enrollment Form

### Instructions:

Pomalidomide is available only through the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS), a restricted distribution program. Only prescribers, pharmacies, and patients enrolled in the Pomalidomide REMS can prescribe, dispense, and receive pomalidomide.

Dispensing of pomalidomide is limited to certified pharmacies. These pharmacies must enroll in the Pomalidomide REMS in order to dispense pomalidomide. If you have any questions about the Pomalidomide REMS, please call 1-866-245-7925. You must designate an authorized representative to complete and submit this form on behalf of this pharmacy.

### Instructions for Authorized Representative:

1. Review the **Prescribing Information**, **Pharmacy Training**, and **Pharmacy Guide**.
2. Complete and submit this **Pharmacy Enrollment Form** and fax it to the Pomalidomide REMS at 1-844-872-5446 or complete it online at [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com).
3. Successfully pass the **Pharmacy Certification Quiz**.

Complete all fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the Pomalidomide REMS will notify the pharmacy upon successful certification.

### AUTHORIZED REPRESENTATIVE RESPONSIBILITIES

I am the Authorized Representative designated by my pharmacy to carry out the certification process and oversee implementation of and compliance with the Pomalidomide REMS. By signing this form, I agree to comply with the requirements of the Pomalidomide REMS and as the Authorized Representative, understand that my pharmacy must also comply with the Pomalidomide REMS requirements:

1. Review the Prescribing Information, **Pharmacy Training** and the **Pharmacy Guide**.
2. Enroll in the REMS by completing the **Pharmacy Enrollment Form** and submitting it to the Pomalidomide REMS.
3. Train all relevant staff involved in counseling and dispensing pomalidomide using the **Pharmacy Guide**, **Pharmacy Training** and the **Education and Counseling Checklist for Pharmacies** and maintain a record of training.
4. Successfully pass the **Pharmacy Certification Quiz**.
5. Establish processes and procedures to verify there are 7 days or less remaining on the patient's existing prescription, no more than 28 days' supply is dispensed, and the prescriber provided the authorization number and patient risk category on the prescription.
6. Inform the Pomalidomide REMS if the Authorized Representative changes and complete a new **Pharmacy Enrollment Form** with the new Authorized Representative.

Before dispensing, I will ensure that all pharmacy staff must:

1. Counsel all patients on the benefits and risks of pomalidomide using the **Education and Counseling Checklist for Pharmacies**.
  - a. For females (adult and children) who can get pregnant: Counsel the patient on the embryo-fetal toxicity with exposure to pomalidomide and her safe-use conditions.
  - b. For adult females who cannot get pregnant: Counsel the patient on safe-use requirements.
  - c. For female children who cannot get pregnant: Counsel the patient to inform the prescriber when menses begins, and on safe use requirements.
  - d. For males (adult and children): Counsel the patient on the embryo-fetal toxicity with exposure to pomalidomide and additional safe-use requirements.
2. Verify that a prescription authorization number and patient risk category are documented on each prescription through the processes and procedures established as a requirement of the REMS program.
3. Obtain confirmation number to dispense each prescription by contacting the REMS program to verify the prescriber is certified, the patient is enrolled and is not pregnant, and the authorization number is valid.
4. Document the confirmation number and the date it was obtained on the prescription.
5. Complete the **Education and Counseling Checklist for Pharmacies**. Retain a completed copy in the patient's record.

# POMALIDOMIDE REMS

## Pharmacy Enrollment Form

### AUTHORIZED REPRESENTATIVE RESPONSIBILITIES (Continued)

6. Dispense no more than a 28 days' supply.
7. Dispense only if there are 7 days or less remaining on the existing prescription.
8. Do not accept verbal prescription orders over the phone.
9. Do not dispense refills.
10. Ship dispensed product within 24 hours of receiving the confirmation number or it must be picked up within 24 hours of obtaining the confirmation number.
11. For females (adult and children) who can get pregnant: Ship pomalidomide the same day the confirmation number is obtained or it must be picked up within 24 hours of obtaining the confirmation number.

At all times, I will ensure that all pharmacy staff must:

1. Report pregnancies immediately to the Pomalidomide REMS.
2. Do not distribute, transfer, loan, or sell pomalidomide, except with the permission of the Pomalidomide REMS.
3. Maintain records of each prescription dispensed with the corresponding confirmation number, date it was obtained, and completed [Education and Counseling Checklist for Pharmacies](#).
4. Comply with audits carried out by the Pomalidomide REMS to ensure that all processes and procedures are in place and are being followed.
5. Accept unused product from the patient or the prescriber.
6. Return unused product from the patient or the prescriber to the Pomalidomide REMS.
7. Maintain records documenting staff's completion of Pomalidomide REMS training.
8. Maintain and make available appropriate documentation reflecting that all processes and procedures are in place and are being followed for the Pomalidomide REMS.

I understand and acknowledge that I must maintain compliance with the requirements of the Pomalidomide REMS; otherwise, my pharmacy will no longer have the ability to dispense pomalidomide.

### PHARMACY INFORMATION All fields must be completed

Pharmacy Name:

Pharmacy Address 1:

City:

State:

ZIP Code:

Pharmacy Address 2:

Pharmacy National Provider Information # (NPI):

### PHARMACY AUTHORIZED REPRESENTATIVE INFORMATION

First Name:

Last Name:

Telephone Number:

Alternate Telephone Number:

Office Fax Number:

Email:

Preferred Method of Contact:

Authorized Representative Signature:

Date:



## POMALIDOMIDE REMS

# Patient-Physician Agreement Form Adult Female Who Can Get Pregnant

For real-time processing of the **Patient-Physician Agreement Form**, go to [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) to submit the form online. To submit this form via fax, please complete all required fields below and fax all pages to the Pomalidomide REMS at 1-844-872-5446.

Please read the following statements carefully.

**Your healthcare provider has prescribed pomalidomide for you. Pomalidomide is available only through a restricted distribution program called the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS). Before taking pomalidomide, patients must read and agree to all of the instructions in the Pomalidomide REMS.**

**Pomalidomide can cause birth defects in an unborn baby. If you are pregnant or become pregnant while taking pomalidomide, it is important for you to know that your unborn baby can have severe birth defects or even die. You must use effective contraception if you are going to have sex.**

Blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism) can happen if you take pomalidomide. For more information, please see the pomalidomide Medication Guide.

### INSTRUCTIONS:

**Before starting your treatment with pomalidomide, you must:**

1. Receive counseling from your prescriber
2. Read the **Patient Guide** and the **Emergency Contraception Brochure**
3. Use contraception and not get pregnant as described in the **Patient Guide**
4. Get a pregnancy test as directed by your prescriber
  - 10-14 days prior to initiation of pomalidomide therapy
  - Within 24 hours of the initial prescription
5. Complete this **Patient-Physician Agreement Form** with your doctor
6. Keep a copy of this form for your records
7. Complete the patient survey
8. Receive counseling from the pharmacy that will send you pomalidomide

For more information, visit [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) or call the Pomalidomide REMS at **1-866-245-7925**.

**Authorized Representatives:** If an authorized representative does not have the power of attorney, a signed and dated letter from the prescriber, on the prescriber's letterhead must be submitted to the Pomalidomide REMS, along with the **Patient-Physician Agreement Form**. This letter must also contain the following: a statement that the incompetent patient lacks the capacity to complete the **Patient-Physician Agreement Form**, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the Pomalidomide REMS and is authorized to consent to treatment with pomalidomide on behalf of the patient.

### PATIENT INFORMATION All fields must be completed

First Name:	Last Name:	Date of Birth (MM/DD/YYYY):		
Street Address:	City:	State:	ZIP Code:	
Telephone Number:	Mobile Phone Number:			
Email Address:	Preferred Contact Method: <input type="checkbox"/> Mobile Phone <sup>1</sup> <input type="checkbox"/> Email			
Diagnosis:	Risk Category: <input type="checkbox"/> Menstruating <input type="checkbox"/> Surgical Menopause <input type="checkbox"/> Natural Menopause (24 months)			

### PRESCRIBER INFORMATION

First Name:	Last Name:	NPI:		
Street Address:	City:	State:	ZIP Code:	
Telephone Number:	Email Address:	Fax Number:		

<sup>1</sup>Please note, for survey reminders sent via text, text-messaging rates may apply.

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form for an Adult Female Who Can Get Pregnant

### SECTION 1. PATIENT AGREEMENT

#### I understand and confirm that:

- Pomalidomide can cause severe birth defects or death to my unborn baby if I am pregnant or become pregnant during treatment
- I am not pregnant now and will not get pregnant while being treated with pomalidomide
- It is possible for me to get pregnant if:
  - o I am having my period (am menstruating), or
  - o My period has stopped because of my treatment
  - o And I have sex with a male
- Not having sex is the **only** birth control method that is 100% effective
- I am not breastfeeding now and will not breastfeed while being treated with pomalidomide
- My pomalidomide prescription is **only** for me and is not to be shared with anyone
- I have read and understood the [Patient Guide](#), [Emergency Contraception Brochure](#) and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that pomalidomide may cause
- My healthcare provider has reviewed this information with me and answered any questions I have asked
- I may be contacted by the Pomalidomide REMS to assist with the Pomalidomide REMS
- I will use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** I have sex with a male unless otherwise recommended by my healthcare provider. My healthcare provider may recommend that I use **at the same time** 2 different birth control methods **every time** I have sex with a male if I cannot use a hormonal or intrauterine device (IUD) method

#### Highly 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)



#### Additional Effective Birth Control Methods

Male latex or synthetic condom  
Diaphragm  
Cervical cap

Not having any sex is the only birth control that is 100% effective. 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).

### PATIENT INFORMATION

Patient Name:	Patient Date of Birth (MM/DD/YYYY):
Prescriber Name:	NPI:

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form for an Adult Female Who Can Get Pregnant

### SECTION 1. PATIENT AGREEMENT (continued)

- I will use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** I have sex with a male:
  - o Starting at least 4 weeks before taking pomalidomide
  - o While taking pomalidomide
  - o During breaks (dose interruptions)
  - o For at least 4 weeks after stopping pomalidomide
- I will have pregnancy tests- performed by my healthcare provider- according to the schedule listed below:
  - o Before treatment initiation (first prescription):
    - 10-14 days prior to initiation of pomalidomide therapy
    - Within 24 hours of the initial prescription
  - o During treatment:
    - Weekly during the first 4 weeks of use
    - Thereafter,
      - Every 4 weeks for female patients who can get pregnant with regular menstrual cycles
      - Every 2 weeks for female patients who can get pregnant with irregular menstrual cycles
- I will have these pregnancy tests even if I do not get my period because of my treatment
- I will need to take another pregnancy test performed by my doctor if my medication is not dispensed within 7 days of taking my pregnancy test
- I will stop taking pomalidomide and call my healthcare provider right away if:
  - o I become pregnant while taking pomalidomide, or
  - o I miss my period or have unusual menstrual bleeding, or
  - o I stop using birth control, or
  - o I think **-for any reason-** that I am pregnant or may be pregnant

If my healthcare provider is not available, I will call the Pomalidomide REMS at **1-866-245-7925**.
- I will stop taking pomalidomide immediately and call my healthcare provider right away if I have sex with a male without using birth control or if I think my birth control has failed. My healthcare provider will discuss my options, which may include emergency birth control. If I become pregnant or think I may be pregnant, and my healthcare provider is not available, I will call the Pomalidomide REMS
- I will complete the mandatory confidential monthly survey while taking pomalidomide (online or by telephone interview)
- I will keep my pomalidomide prescription out of the reach of children
- I will **not** share my pomalidomide capsules with anyone
- I will not break, chew, or open my pomalidomide capsules
- I will return any unused pomalidomide capsules for disposal. Unused pomalidomide capsules can be returned to the Pomalidomide REMS, my prescriber, or the pharmacy that dispensed my pomalidomide
- I will **not** donate blood while taking pomalidomide (including dose interruptions) and for 4 weeks after stopping pomalidomide

### PATIENT INFORMATION

Patient Name:	Patient Date of Birth (MM/DD/YYYY):
Prescriber Name:	NPI:

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form for an Adult Female Who Can Get Pregnant

### Section 2. Patient Authorization

#### I understand and confirm that:

- By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with the Pomalidomide REMS Applicants and other companies they work with to:
  - o Coordinate the delivery of products and services available from pharmacies and patient assistance programs, and other companies
  - o Analyze data for internal business purposes on the use of pomalidomide
  - o Evaluate the effectiveness of the Pomalidomide REMS
  - o Use in any other manner as required or permitted by law
  - o Provide me with information about pomalidomide or my condition
- This authorization will remain in effect for 12 months after I stop pomalidomide. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the Pomalidomide REMS
- Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want to participate in the Pomalidomide REMS. I understand that by refusing to participate in the Pomalidomide REMS, I will not be able to receive pomalidomide. However, I understand that I can speak with my healthcare provider about other treatment options for my condition
- Upon signing this form, **I authorize my healthcare provider to begin my treatment with pomalidomide**

### SECTION 3. AUTHORIZATION TO START TREATMENT

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the Pomalidomide REMS, I will not be able to receive pomalidomide. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the Pomalidomide REMS Applicants and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if she has any questions regarding her treatment with, including the use of two methods of effective birth control (at least one highly effective method and one effective method) at the same time, and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the Pomalidomide REMS**

### PATIENT AUTHORIZATION

All fields must be completed

Patient Name:	Patient Date of Birth (MM/DD/YYYY):
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 Patient or Parent/Guardian Signature:	Date:
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### PRESCRIBER AUTHORIZATION

Prescriber Name:	NPI:
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 Prescriber Signature:	Date:
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**A copy of this form should be provided to the patient.**

For real-time processing of the **Patient-Physician Agreement Form**, go to [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) to submit the form online.  
To submit this form via fax, please complete all required fields and fax all pages to the Pomalidomide REMS at 1-844-872-5446.

**POMALIDOMIDE REMS**

## POMALIDOMIDE REMS

# Patient-Physician Agreement Form Female Child Who Can Get Pregnant

For real-time processing of the **Patient-Physician Agreement Form**, go to [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) to submit the form online. To submit this form via fax, please complete all required fields below and fax all pages to the Pomalidomide REMS at 1-844-872-5446.

Please read the following statements carefully. *Throughout this form, the word 'child' includes any child of whom you are the parent or guardian.*

**Your healthcare provider has prescribed pomalidomide for your child. Pomalidomide is available only through a restricted distribution program called the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS). Before taking pomalidomide, patients must read and agree to all of the instructions in the Pomalidomide REMS.**

**Pomalidomide can cause birth defects in an unborn baby. If your child is pregnant or becomes pregnant while taking pomalidomide, it is important to know that the unborn baby can have severe birth defects or even die. Your child must use effective contraception if she is going to have sex.**

Blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism) can happen if you take pomalidomide. For more information, please see the pomalidomide Medication Guide.

### INSTRUCTIONS:

**Before your child starts treatment with pomalidomide, you/your child must:**

1. Receive counseling from the prescriber
2. Read the **Patient Guide** and the **Emergency Contraception Brochure**
3. Use contraception and not get pregnant as described in the **Patient Guide**
4. Get a pregnancy test as directed by the prescriber
5. Complete this **Patient-Physician Agreement Form** with your child's doctor
6. Keep a copy of this form for your records
7. Complete the patient survey
8. Receive counseling from the pharmacy that will send your child pomalidomide

For more information, visit [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) or call the Pomalidomide REMS at **1-866-245-7925**.

### PATIENT INFORMATION All fields must be completed

First Name:	Last Name:	Date of Birth (MM/DD/YYYY):		
Street Address:	City:	State:	ZIP Code:	
Telephone Number:	Mobile Phone Number:			
Email Address:	Preferred Contact Method: <input type="checkbox"/> Mobile Phone <sup>1</sup> <input type="checkbox"/> Email			
Diagnosis:	Risk Category: <input type="checkbox"/> Menstruating <input type="checkbox"/> Surgical Menopause <input type="checkbox"/> Natural Menopause (24 months)			

### PRESCRIBER INFORMATION

First Name:	Last Name:	NPI:		
Street Address:	City:	State:	ZIP Code:	
Telephone Number:	Email Address:	Fax Number:		

<sup>1</sup>Please note, for survey reminders sent via text, text-messaging rates may apply.

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form for a Female Child Who Can Get Pregnant

### SECTION 1. PATIENT AGREEMENT

#### I understand and confirm that:

- Pomalidomide can cause severe birth defects or death to my child's unborn baby if my child is pregnant or becomes pregnant during treatment
- My child is not pregnant and will not get pregnant while being treated with pomalidomide
- It is possible for my child to get pregnant if:
  - o She has her period (is menstruating) or has shown any sign of puberty, or
  - o Her period has stopped because of treatment
  - o And she has sex with a male
- Not having sex is the **only** birth control method that is 100% effective
- My child is not breastfeeding and will not breastfeed while being treated with pomalidomide
- My child's pomalidomide prescription is **only** for her and is not to be shared with others
- We have read and understood the **Patient Guide, Emergency Contraception Brochure** and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that pomalidomide may cause
- My child's healthcare provider has reviewed this information with us and answered any questions we have asked
- We may be contacted by the Pomalidomide REMS to assist with the Pomalidomide REMS
- My child will NOT donate blood while taking pomalidomide (including dose interruptions) and for 4 weeks after stopping pomalidomide

#### I will tell my child that:

- She must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** she has sex with a male unless otherwise recommended by her healthcare provider. Her healthcare provider may recommend that she use **at the same time** 2 different birth control methods **every time** she has sex with a male if she cannot use a hormonal or intrauterine device (IUD) method.

Unless she chooses not to have sexual intercourse with a male at any time (abstinence), she must always use acceptable birth control

#### Highly 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)



#### Additional Effective Birth Control Methods

Male latex or synthetic condom  
 Diaphragm  
 Cervical cap

**Not having any sex is the only birth control that is 100% effective. 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).**

- She must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** she has sex with a male:
  - o Starting at least 4 weeks before taking pomalidomide
  - o While taking pomalidomide
  - o During breaks (dose interruptions)
  - o For at least 4 weeks after stopping pomalidomide

### PATIENT INFORMATION

Patient Name:	Patient Date of Birth (MM/DD/YYYY):
Prescriber Name:	NPI:

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form for a Female Child Who Can Get Pregnant

### I will tell my child that:

- She must have pregnancy tests- performed by her healthcare provider- according to the schedule listed below:
  - o Before treatment initiation (first prescription):
    - 10-14 days prior to initiation of pomalidomide therapy
    - Within 24 hours of the initial prescription
  - o During treatment:
    - Weekly during the first 4 weeks of use
    - Thereafter,
      - Every 4 weeks for female patients who can get pregnant with regular menstrual cycles
      - Every 2 weeks for female patients who can get pregnant with irregular menstrual cycles
- She must have these pregnancy tests even if she does not get her period because of her treatment
- She must take another pregnancy test performed by her doctor if her medication is not dispensed within 7 days of taking her pregnancy test
- She must stop taking pomalidomide and call her healthcare provider right away if:
  - o She becomes pregnant while taking pomalidomide, or
  - o She misses her period or has unusual menstrual bleeding, or
  - o She stops using birth control, or
  - o She thinks **-for any reason-** that she is pregnant or may be pregnant

If my child's healthcare provider is not available, I will call the Pomalidomide REMS at **1-866-245-7925**

She must stop taking pomalidomide immediately and you should call her healthcare provider right away if she has sex with a male without using birth control or if she thinks her birth control has failed. Her healthcare provider will discuss her options, which may include emergency birth control. If she becomes pregnant or thinks she may be pregnant, and her healthcare provider is not available, I will call the Pomalidomide REMS at **1-866-245-7925**.

- We will complete the mandatory confidential monthly survey while she is taking pomalidomide (online or by telephone interview)
- We will keep my child's pomalidomide prescription out of the reach of other children
- She must **not** share her pomalidomide capsules with anyone
- She will not break, chew, or open her pomalidomide capsules
- We will return any unused pomalidomide capsules for disposal. Unused pomalidomide capsules can be returned to the Pomalidomide REMS, her prescriber, or the pharmacy that dispensed her pomalidomide
- She must **not** donate blood while taking pomalidomide (including dose interruptions) and for 4 weeks after stopping pomalidomide

### PATIENT INFORMATION

Patient Name:	Patient Date of Birth (MM/DD/YYYY):
Prescriber Name:	NPI:

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form for a Female Child Who Can get Pregnant

### SECTION 2. PATIENT AUTHORIZATION

**I understand and confirm that:**

- By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with the Pomalidomide REMS Applicants and other companies they work with to:
  - o Coordinate the delivery of products and services available from pharmacies and patient assistance programs, and other companies
  - o Analyze data for internal business purposes on the use of pomalidomide
  - o Evaluate the effectiveness of the Pomalidomide REMS
  - o Use in any other manner as required or permitted by law
  - o Provide me and my child with information about pomalidomide or my child's condition
- This authorization will remain in effect for 12 months after my child stops pomalidomide. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the Pomalidomide REMS
- Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want my child to participate in the Pomalidomide REMS. I understand that by refusing to have my child participate in the Pomalidomide REMS, she will not be able to receive pomalidomide. However, I understand that I can speak with my child's healthcare provider about other treatment options for my child's condition
- Upon signing this form, **I authorize my child's healthcare provider to begin my child's treatment with pomalidomide**

### SECTION 3. AUTHORIZATION TO START TREATMENT

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the Pomalidomide REMS, she will not be able to receive pomalidomide. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the Pomalidomide REMS Applicants and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient and her parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and her parent/guardian if they have any questions regarding the child's treatment with, including the use of two methods of birth control (at least one highly effective method and one effective method) at the same time, and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the Pomalidomide REMS.**

#### PATIENT AUTHORIZATION

All fields must be completed

Patient Name:		Patient Date of Birth (MM/DD/YYYY):	
Patient or Parent/Guardian Signature:		Date:	

#### PRESCRIBER AUTHORIZATION

Prescriber Name:		NPI:	
Prescriber Signature:		Date:	

**A copy of this form should be provided to the patient.**

For real-time processing of the **Patient-Physician Agreement Form**, go to [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) to submit the form online. To submit this form via fax, please complete all required fields and fax all pages to the Pomalidomide REMS at 1-844-872-5446.

**POMALIDOMIDE REMS**

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form Adult Females Who Cannot Get Pregnant

For real-time processing of the **Patient-Physician Agreement Form**, go to [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) to submit the form online. To submit this form via fax, please complete all required fields below and fax all pages to the Pomalidomide REMS at 1-844-872-5446.

Please read the following statements carefully.

**Your healthcare provider has prescribed pomalidomide for you. Pomalidomide is available only through a restricted distribution program called the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS). Before taking pomalidomide, patients must read and agree to all of the instructions in the Pomalidomide REMS.**

**Pomalidomide can cause birth defects in an unborn baby. Any unborn baby of a female taking pomalidomide can have severe birth defects or even die.**

Blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism) can happen if you take pomalidomide. For more information, please see the pomalidomide Medication Guide.

### Instructions:

**Before starting your treatment with pomalidomide, you must:**

1. Receive counseling from your prescriber
2. Read the **Patient Guide**
3. Complete this **Patient-Physician Agreement Form** with your doctor
4. Keep a copy of this form for your records
5. Complete the patient survey
6. Receive counseling from the pharmacy that will send you pomalidomide

For more information, visit [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) or call the Pomalidomide REMS at **1-866-245-7925**.

**Authorized Representatives:** If an authorized representative does not have the power of attorney, a signed and dated letter from the prescriber, on the prescriber's letterhead must be submitted to the Pomalidomide REMS, along with the **Patient-Physician Agreement Form**. This letter must also contain the following: a statement that the incompetent patient lacks the capacity to complete the **Patient-Physician Agreement Form**, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the Pomalidomide REMS and is authorized to consent to treatment with pomalidomide on behalf of the patient.

### PATIENT INFORMATION All fields must be completed

First Name:	Last Name:	Date of Birth (MM/DD/YYYY):		
Street Address:	City:	State:	ZIP Code:	
Telephone Number:	Mobile Phone Number:			
Email Address:	Preferred Contact Method: <input type="checkbox"/> Mobile Phone <sup>1</sup> <input type="checkbox"/> Email			
Diagnosis:	Risk Category: <input type="checkbox"/> Menstruating <input type="checkbox"/> Surgical Menopause <input type="checkbox"/> Natural Menopause (24 months)			

### PRESCRIBER INFORMATION

First Name:	Last Name:	NPI:		
Street Address:	City:	State:	ZIP Code:	
Telephone Number:	Email Address:	Fax Number:		

<sup>1</sup>Please note, for survey reminders sent via text, text-messaging rates may apply.

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form Adult Females Who Can Not Get Pregnant

### SECTION 1. PATIENT AGREEMENT

**I understand and confirm that:**

- Pomalidomide can cause severe birth defects or death to unborn babies of females taking pomalidomide
- I am not pregnant
- I am not able to get pregnant because:
  - o I have had both of my ovaries and/or my uterus removed, or
  - o I have been in natural menopause for at least 2 years
- My pomalidomide prescription is **only** for me and is not to be shared with anyone
- I have read and understood the **Patient Guide** and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that pomalidomide may cause
- My healthcare provider has reviewed this information with me and answered any questions I have asked
- I may be contacted by the Pomalidomide REMS to assist with the Pomalidomide REMS
- I will complete the mandatory confidential survey every 6 months while taking pomalidomide (online or by telephone interview)
- I will keep my pomalidomide prescription out of the reach of children
- I will not break, chew, or open my pomalidomide capsules
- I will return any unused pomalidomide capsules for disposal. Unused pomalidomide capsules can be returned to the Pomalidomide REMS, my prescriber, or the pharmacy that dispensed my pomalidomide
- I will **not** share my pomalidomide capsules with anyone
- I will **not** donate blood while taking pomalidomide (including dose interruptions) and for 4 weeks after stopping pomalidomide

### PATIENT INFORMATION

Patient Name:	Patient Date of Birth (MM/DD/YYYY):
Prescriber Name:	NPI:

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form Adult Females Who Can Not Get Pregnant

### Section 2. Patient Authorization

#### I understand and confirm that:

- By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with the Pomalidomide REMS Applicants and other companies they work with to:
  - o Coordinate the delivery of products and services available from pharmacies and patient assistance programs, and other companies
  - o Analyze data for internal business purposes on the use of pomalidomide
  - o Evaluate the effectiveness of the Pomalidomide REMS
  - o Use in any other manner as required or permitted by law
  - o Provide me with information about pomalidomide or my condition
- This authorization will remain in effect for 12 months after I stop pomalidomide. However it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the Pomalidomide REMS
- Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want to participate in the Pomalidomide REMS. I understand that by refusing to participate in the Pomalidomide REMS, I will not be able to receive pomalidomide. However, I understand that I can speak with my healthcare provider about other treatment options for my condition
- Upon signing this form, **I authorize my healthcare provider to begin my treatment with pomalidomide**

### SECTION 3. AUTHORIZATION TO START TREATMENT

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the Pomalidomide REMS, I will not be able to receive pomalidomide. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the Pomalidomide REMS Applicants and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if she has any questions regarding her treatment with pomalidomide and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the Pomalidomide REMS.**

### PATIENT AUTHORIZATION

All fields must be completed

Patient Name:	Patient Date of Birth (MM/DD/YYYY):
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 Patient or Parent/Guardian Signature:	Date:
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### PRESCRIBER AUTHORIZATION

Prescriber Name:	NPI:
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 Prescriber Signature:	Date:
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**A copy of this form should be provided to the patient.**

For real-time processing of the **Patient-Physician Agreement Form**, go to [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) to submit the form online. To submit this form via fax, please complete all required fields below and fax all pages to the Pomalidomide REMS at 1- 844-872-5446.

**POMALIDOMIDE REMS**

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form Female Child Who Cannot Get Pregnant

For real-time processing of the **Patient-Physician Agreement Form**, go to [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) to submit the form online. To submit this form via fax, please complete all required fields below and fax all pages to the Pomalidomide REMS at 1-844-872-5446.

Please read the following statements carefully. *Throughout this form, the word 'child' includes any child of whom you are the parent or guardian.*

**Your healthcare provider has prescribed pomalidomide for your child. Pomalidomide is available only through a restricted distribution program called the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS). Before taking pomalidomide, patients must read and agree to all of the instructions in the Pomalidomide REMS.**

**Pomalidomide can cause birth defects in an unborn baby. Any unborn baby of a girl taking pomalidomide can have severe birth defects or even die.**

Blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism) can happen if you take pomalidomide. For more information, please see the pomalidomide Medication Guide.

### INSTRUCTIONS:

**Before your child starts treatment with pomalidomide, you/your child must:**

1. Receive counseling from the prescriber
2. Read the [Patient Guide](#)
3. Complete this **Patient-Physician Agreement Form** with your child's doctor
4. Keep a copy of this form for your records
5. Complete the patient survey
6. Receive counseling from the pharmacy that will send your child pomalidomide

For more information, visit [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) or call the Pomalidomide REMS at **1-866-245-7925**.

PATIENT INFORMATION				
All fields must be completed				
First Name:	Last Name:		Date of Birth (MM/DD/YYYY):	
Street Address:		City:	State:	ZIP Code:
Telephone Number:		Mobile Phone Number:		
Email Address:		Preferred Contact Method: <input type="checkbox"/> Mobile Phone <sup>1</sup> <input type="checkbox"/> Email		
Diagnosis:				
PRESCRIBER INFORMATION				
First Name:	Last Name:		NPI:	
Street Address:		City:	State:	ZIP Code:
Telephone Number:		Email Address:	Fax Number:	

<sup>1</sup>Please note, for survey reminders sent via text, text-messaging rates may apply.

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form for a Female Child Who Can Not Get Pregnant

### SECTION 1. PATIENT AGREEMENT

#### I understand and confirm that:

- Pomalidomide can cause severe birth defects or death to unborn babies of females taking pomalidomide
- My child is not pregnant
- My child is not able to get pregnant because she has not yet started her period (is not menstruating)
- My child's pomalidomide prescription is **only** for her and is not to be shared with others
- We have read and understood the **Patient Guide** and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that pomalidomide may cause
- My child's healthcare provider has reviewed this information with us and answered any questions we have asked
- We may be contacted by the Pomalidomide REMS to assist with the Pomalidomide REMS

#### I will tell my child that:

- We will complete the mandatory confidential monthly survey while my child is taking pomalidomide (online or by telephone interview)
- We will keep my child's pomalidomide prescription out of the reach of other children
- She will not break, chew, or open her pomalidomide capsules
- We will return any unused pomalidomide capsules for disposal. Unused pomalidomide capsules can be returned to the Pomalidomide REMS, her prescriber, or the pharmacy that dispensed her pomalidomide
- She must **not** share pomalidomide capsules with anyone
- She must **not** donate blood while taking pomalidomide (including dose interruptions) and for 4 weeks after stopping pomalidomide

### SECTION 2. PATIENT AUTHORIZATION

#### I understand and confirm that:

- By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with the Pomalidomide REMS Applicants and other companies they work with to:
  - o Coordinate the delivery of products and services available from pharmacies and patient assistance programs, and other companies
  - o Analyze data for internal business purposes on the use of pomalidomide
  - o Evaluate the effectiveness of the Pomalidomide REMS
  - o Use in any other manner as required or permitted by law
  - o Provide me and my child with information about pomalidomide or my child's condition
- This authorization will remain in effect for 12 months after my child stops pomalidomide. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the Pomalidomide REMS
- Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want my child to participate in the Pomalidomide REMS. I understand that by refusing to have my child participate in the Pomalidomide REMS, she will not be able to receive pomalidomide. However, I understand that I can speak with my child's healthcare provider about other treatment options for my child's condition
- Upon signing this form, I **authorize my child's healthcare provider to begin my child's treatment with pomalidomide**

### PATIENT INFORMATION

Patient Name:	Patient Date of Birth (MM/DD/YYYY):
Prescriber Name:	NPI:

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form for a Female Child Who Can Not Get Pregnant

### SECTION 3. AUTHORIZATION TO START TREATMENT

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the Pomalidomide REMS, she will not be able to receive pomalidomide. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the Pomalidomide REMS Applicants and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient and her parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and her parent/guardian if they have any questions regarding the child's treatment with pomalidomide and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the Pomalidomide REMS.**

### PATIENT AUTHORIZATION

All fields must be completed

Patient Name:	Patient Date of Birth (MM/DD/YYYY):	
Patient or Parent/Guardian Signature:		Date:

### PRESCRIBER AUTHORIZATION

Prescriber Name:	NPI:	
Prescriber Signature:		Date:

**A copy of this form should be provided to the patient.**

For real-time processing of the **Patient-Physician Agreement Form**, go to [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) to submit the form online. To submit this form via fax, please complete all required fields and fax all pages to the Pomalidomide REMS at 1-844-872-5446.

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form Adult Male

For real-time processing of the **Patient-Physician Agreement Form**, go to [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) to submit the form online. To submit this form via fax, please complete all required fields below and fax all pages to the Pomalidomide REMS at 1-844-872-5446.

Please read the following statements carefully.

**Your healthcare provider has prescribed pomalidomide for you. Pomalidomide is available only through a restricted distribution program called the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS). Before taking pomalidomide, you must read and agree to all of the instructions in the Pomalidomide REMS.**

**Pomalidomide can cause birth defects in an unborn baby. If a female you have sex with is pregnant or becomes pregnant by you while you are taking pomalidomide, it is important for you to know that your unborn baby can have severe birth defects or even die. You must use effective contraception if you are going to have sex.**

Blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism) can happen if you take pomalidomide. For more information, please see the pomalidomide Medication Guide.

### INSTRUCTIONS:

**Before starting your treatment with pomalidomide, you must:**

1. Receive counseling from your prescriber
2. Read the [Patient Guide](#) and the [Emergency Contraception Brochure](#)
3. Complete this **Patient-Physician Agreement Form** with your doctor
4. Keep a copy of this form for your records
5. Receive counseling from the pharmacy that will send you pomalidomide

For more information, visit [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) or call the Pomalidomide REMS at **1-866-245-7925**.

**Authorized Representatives:** If an authorized representative does not have the power of attorney, a signed and dated letter from the prescriber, on the prescriber's letterhead must be submitted to the Pomalidomide REMS, along with the Patient-Physician Agreement Form. This letter must also contain the following: a statement that the incompetent patient lacks the capacity to complete the **Patient-Physician Agreement Form**, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the Pomalidomide REMS and is authorized to consent to treatment with pomalidomide on behalf of the patient.

### PATIENT INFORMATION All fields must be completed

First Name:	Last Name:	Date of Birth (MM/DD/YYYY):		
Street Address:	City:	State:	ZIP Code:	
Telephone Number:	Mobile Phone Number:			
Email Address:	Preferred Contact Method: <input type="checkbox"/> Mobile Phone <sup>1</sup> <input type="checkbox"/> Email			
Diagnosis:				

### PRESCRIBER INFORMATION

First Name:	Last Name:	NPI:		
Street Address:	City:	State:	ZIP Code:	
Telephone Number:	Email Address:	Fax Number:		

<sup>1</sup>Please note, for survey reminders sent via text, text-messaging rates may apply.

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form for an Adult Male

### SECTION 1. PATIENT AGREEMENT

#### I understand and confirm that:

- Pomalidomide can cause severe birth defects or death to my unborn baby if I have sex with a female who is pregnant or who is able to get pregnant during my treatment
- My semen may contain pomalidomide even after I stop treatment
- I must use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant:
  - o While taking pomalidomide
  - o During breaks (dose interruptions)
  - o For 4 weeks after stopping pomalidomide
- I must use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant, even if I have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- Not having sex is the **only** birth control method that is 100% effective
- My pomalidomide prescription is **only** for me and is not to be shared with others
- I have read and understood the [Patient Guide](#), [Emergency Contraception Brochure](#) and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that pomalidomide may cause
- My healthcare provider has reviewed this information with me and answered any questions I have asked
- I may be contacted by the Pomalidomide REMS to assist with the Pomalidomide REMS
- I will call my healthcare provider right away if:
  - o I have unprotected sex with a female who is pregnant or who is able to get pregnant
  - o I think -for any reason- that my sexual partner is pregnant or may be pregnant
  - o My partner becomes pregnant or thinks she may be pregnantIf my healthcare provider is not available I will call the Pomalidomide REMS at **1- 866-245-7925**
- I will complete the mandatory confidential monthly survey while taking pomalidomide (online or by telephone interview), even though I will not have to take a survey for my first prescription
- I will keep my pomalidomide prescription out of the reach of children
- I will not break, chew, or open my pomalidomide capsules
- I will return any unused pomalidomide capsules for disposal. Unused pomalidomide capsules can be returned to the Pomalidomide REMS, my prescriber, or the pharmacy that dispensed my pomalidomide
- I will **not** share my pomalidomide capsules with anyone
- I will **not** donate blood or sperm while taking pomalidomide, during breaks (dose interruptions), and for 4 weeks after stopping pomalidomide

### PATIENT INFORMATION

Patient Name:	Patient Date of Birth (MM/DD/YYYY):
Prescriber Name:	NPI:

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form for an Adult Male

### I understand and confirm that:

- By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with the Pomalidomide REMS Applicants and other companies they work with to:
  - o Coordinate the delivery of products and services available from pharmacies and patient assistance programs, and other companies
  - o Analyze data for internal business purposes on the use of pomalidomide
  - o Evaluate the effectiveness of the Pomalidomide REMS
  - o Use in any other manner as required or permitted by law
  - o Provide me with information about pomalidomide or my condition
- This authorization will remain in effect for 12 months after I stop pomalidomide. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the Pomalidomide REMS
- Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want to participate in the Pomalidomide REMS. I understand that by refusing to participate in the Pomalidomide REMS, I will not be able to receive pomalidomide. However, I understand that I can speak with my healthcare provider about other treatment options for my condition
- Upon signing this form, I **authorize my healthcare provider to begin my treatment with pomalidomide**

### SECTION 3. AUTHORIZATION TO START TREATMENT

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the Pomalidomide REMS, I will not be able to receive pomalidomide. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the Pomalidomide REMS Applicants and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if he has any questions regarding his treatment with pomalidomide (including appropriate birth control methods) and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the Pomalidomide REMS.**

### PATIENT AUTHORIZATION

All fields must be completed

Patient Name:	Patient Date of Birth (MM/DD/YYYY):
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Patient or Parent/Guardian Signature:	Date:
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### PRESCRIBER AUTHORIZATION

Prescriber Name:	NPI:
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Prescriber Signature:	Date:
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**A copy of this form should be provided to the patient.**

For real-time processing of the **Patient-Physician Agreement Form**, go to [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) to submit the form online. To submit this form via fax, please complete all required fields and fax all pages to the Pomalidomide REMS at 1-844-872-5446.

**POMALIDOMIDE REMS**

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form Male Child

For real-time processing of the **Patient-Physician Agreement Form**, go to [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) to submit the form online. To submit this form via fax, please complete all required fields below and fax all pages to the Pomalidomide REMS at 1-844-872-5446.

Please read the following statements carefully. *Throughout this form, the word 'child' includes any child of whom you are the parent or guardian.*

**Your healthcare provider has prescribed pomalidomide for your child. Pomalidomide is available only through a restricted distribution program called the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS). Before taking pomalidomide, patients must read and agree to all of the instructions in the Pomalidomide REMS.**

**Pomalidomide can cause birth defects in an unborn baby. If a female your child has sex with is pregnant or becomes pregnant by your child while he is taking pomalidomide, it is important to know that the unborn baby can have severe birth defects or even die. Your child must use effective contraception if he is going to have sex.**

Blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism) can happen if you take pomalidomide. For more information, please see the pomalidomide Medication Guide.

### INSTRUCTIONS:

**Before your child starts treatment with pomalidomide, you/your child must:**

1. Receive counseling from the prescriber
2. Read the [Patient Guide](#) and the [Emergency Contraception Brochure](#)
3. Complete this **Patient-Physician Agreement Form** with your child's doctor
4. Keep a copy of this form for your records
5. Receive counseling from the pharmacy that will send your child pomalidomide

For more information, visit [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) or call the Pomalidomide REMS at **1-866-245-7925**.

PATIENT INFORMATION				
All fields must be completed				
First Name:	Last Name:	Date of Birth (MM/DD/YYYY):		
Street Address:	City:	State:	ZIP Code:	
Telephone Number:	Mobile Phone Number:			
Email Address:	Preferred Contact Method: <input type="checkbox"/> Mobile Phone <sup>1</sup> <input type="checkbox"/> Email			
Diagnosis:				
PRESCRIBER INFORMATION				
First Name:	Last Name:	NPI:		
Street Address:	City:	State:	ZIP Code:	
Telephone Number:	Fax Number:			
Email Address:				

<sup>1</sup>Please note, for survey reminders sent via text, text-messaging rates may apply.

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form for a Male Child

### SECTION 1. PATIENT AGREEMENT

#### I understand and confirm that:

- Pomalidomide can cause severe birth defects or death to the unborn baby if my child has sex with a female who is pregnant or who is able to get pregnant during his treatment
  - My child's semen may contain pomalidomide even after he stops treatment. He must use a latex or synthetic condom **every time** he has sex with a female who is pregnant or who is able to get pregnant:
    - o While taking pomalidomide
    - o During breaks (dose interruptions)
    - o For 4 weeks after stopping pomalidomide
  - I will tell my child that he must use a latex or synthetic condom **every** time he has sex with a female who is pregnant or who is able to get pregnant, even if he has had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
  - Not having sex is the **only** birth control method that is 100% effective
  - My child's pomalidomide prescription is **only** for him and is not to be shared with others
  - We have read and understood the [Patient Guide](#), [Emergency Contraception Brochure](#) and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that pomalidomide may cause
  - My child's healthcare provider has reviewed this information with us and answered any questions we have asked
  - We may be contacted by the Pomalidomide REMS to assist with the Pomalidomide REMS
  - I will call his healthcare provider right away if:
    - o He has unprotected sex with a female who is pregnant or who is able to get pregnant
    - o He thinks **for any reason**- that his sexual partner is pregnant or may be pregnant
    - o His partner becomes pregnant or thinks she may be pregnant
- If my child's healthcare provider is not available I will call the Pomalidomide REMS at **1-866-245-7925**
- We will complete the mandatory confidential monthly survey while my child is taking pomalidomide (online or by telephone interview), even though we will not have to take a survey for his first prescription
  - We will keep his pomalidomide prescription out of the reach of other children
  - He will not break, chew, or open his pomalidomide capsules
  - We will return any unused pomalidomide capsules for disposal. Unused pomalidomide capsules can be returned to the Pomalidomide REMS, his prescriber, or the pharmacy that dispensed his pomalidomide
  - He must **not** share his pomalidomide capsules with anyone
  - He must **not** donate blood or sperm while taking pomalidomide, during breaks (dose interruptions), and for 4 weeks after stopping pomalidomide

### PATIENT INFORMATION

Patient Name:	Patient Date of Birth (MM/DD/YYYY):
Prescriber Name:	NPI:

# POMALIDOMIDE REMS

## Patient-Physician Agreement Form for a Male Child

### SECTION 2. PATIENT AUTHORIZATION

#### I understand and confirm that:

- By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with the Pomalidomide REMS Applicants and other companies they work with to:
  - Coordinate the delivery of products and services available from pharmacies and patient assistance programs, and other companies
  - Analyze data for internal business purposes on the use of pomalidomide
  - Evaluate the effectiveness of the Pomalidomide REMS
  - Use in any other manner as required or permitted by law
  - Provide me and my child with information about pomalidomide or my child's condition
- This authorization will remain in effect for 12 months after my child stops pomalidomide. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the Pomalidomide REMS
- Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- I may refuse to sign this authorization, which means that I do not want my child to participate in the Pomalidomide REMS. I understand that by refusing to have my child participate in the Pomalidomide REMS, he will not be able to receive pomalidomide. However, I understand that I can speak with my child's healthcare provider about other treatment options for my child's condition
- Upon signing this form, I **authorize my child's healthcare provider to begin my child's treatment with pomalidomide**

### SECTION 3. AUTHORIZATION TO START TREATMENT

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the Pomalidomide REMS, he will not be able to receive pomalidomide. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the Pomalidomide REMS Applicants and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient and his parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and his parent/guardian if they have any questions regarding the child's treatment with pomalidomide (including appropriate birth control methods) and has answered those questions to the patient's, parent/guardian's and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the Pomalidomide REMS.**

#### PATIENT AUTHORIZATION

All fields must be completed

Patient Name:		Patient Date of Birth (MM/DD/YYYY):	
Patient or Parent/Guardian Signature:		Date:	

#### PRESCRIBER AUTHORIZATION

Prescriber Name:		NPI:	
Prescriber Signature:		Date:	

A copy of this form should be provided to the patient.

For real-time processing of the **Patient-Physician Agreement Form**, go to [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) to submit the form online. To submit this form via fax, please complete all required fields and fax all pages to the Pomalidomide REMS at 1-844-872-5446.

## POMALIDOMIDE REMS

# Pomalidomide REMS

Dear Prescriber:

## Enclosed are your Pomalidomide REMS education materials

The Pomalidomide REMS is pleased to provide you with the enclosed materials for use in the Pomalidomide REMS.

Important Information about the Pomalidomide REMS:

- To avoid embryo-fetal exposure, pomalidomide is only available under a restricted distribution program called the Pomalidomide REMS
- Pomalidomide is contraindicated in pregnant females and females capable of becoming pregnant. Females who can get pregnant may be treated with pomalidomide provided adequate precautions are taken to avoid pregnancy
- Male Patients: Clinical data has demonstrated the presence of pomalidomide in human semen. Male patients taking pomalidomide should not donate sperm. Males receiving pomalidomide must always use a latex or synthetic condom during any sexual contact with females who can get pregnant even if they have undergone a successful vasectomy
- Only prescribers and pharmacies certified with the Pomalidomide REMS can prescribe and dispense pomalidomide to patients who are enrolled and meet all the conditions of the Pomalidomide REMS

As a prescriber certified with the Pomalidomide REMS, please review and familiarize yourself with the contents of the enclosed Pomalidomide REMS Education and Prescribing Safety Kit:

- **Prescriber Materials**
  - [Prescriber Guide](#)
  - Prescribing Information\*
    - *\* Please note, the enclosed materials include Prescribing Information from each generic pomalidomide manufacturers participating in the Pomalidomide REMS.*
- **Patient Materials (Patient Resource Pack)**
  - [Patient Guide](#)
  - [Emergency Contraception Brochure](#)
  - Medication Guide\*
    - *\*Please note, the enclosed materials include the Medication Guide from each generic pomalidomide manufacturers participating in the Pomalidomide REMS.*

To order additional Patient Resource Packs, please call the REMS Coordinating Center at 1- 866-245-7925.

Sincerely,

The Pomalidomide REMS

## **About Pomalidomide**

Pomalidomide, in combination with dexamethasone, is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

## **Risks of Pomalidomide**

**Pomalidomide has a Boxed Warning for embryo-fetal toxicity and thromboembolic events, including deep venous thrombosis (DVT) and pulmonary embolism (PE), myocardial infarction and stroke.**

**Due to the fact that it is an analogue of thalidomide, a known teratogen,** pomalidomide is contraindicated in pregnant females or females capable of becoming pregnant. Females of reproductive potential may be treated with pomalidomide if they take adequate precautions to avoid pregnancy.

Deep Venous Thrombosis (DVT), Pulmonary Embolism (PE), myocardial infarction and stroke occur in patients with multiple myeloma treated with pomalidomide.

**This is not a comprehensive description of risks associated with the use of pomalidomide. Please see Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.**

Pomalidomide is approved through a restricted distribution program, approved by the Food and Drug Administration, called the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS).

## POMALIDOMIDE RISK EVALUATION AND MITIGATION STRATEGY (REMS)

# Prescriber Guide

**This guide contains important information for prescribers about:**

- The risks of pomalidomide, including a boxed warning for
  - Embryo-fetal toxicity
  - Venous and arterial thromboembolism
- The Pomalidomide REMS
  - Prescriber Certification
  - Patient Enrollment
  - Contraceptive Requirements and Counseling for Patients
  - Initial and Subsequent Prescription Requirements

**Pomalidomide REMS Resources for Prescribers Include:**

- [Prescriber Guide](#)
- Prescribing Information\*

*\*Please note, the Pomalidomide REMS Education and Prescribing Safety Kit includes Prescribing Information from each generic pomalidomide manufacturer participating in the Pomalidomide REMS.*

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8	Initial Mandatory Confidential Survey
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## Risks of Pomalidomide

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**Because it is an analogue of thalidomide, a known teratogen**, pomalidomide is contraindicated in pregnant females or females capable of becoming pregnant. Females who can get pregnant may be treated with pomalidomide if they take adequate precautions to avoid pregnancy.

Deep Venous Thrombosis (DVT), Pulmonary Embolism (PE), myocardial infarction and stroke occur in patients with multiple myeloma treated with pomalidomide.

**This is not a comprehensive description of risks associated with the use of pomalidomide.**

**Please see Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, for further information.**

## The Pomalidomide REMS

To avoid embryo-fetal exposure, pomalidomide is only available through a restricted distribution program called the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS). Only certified prescribers can prescribe pomalidomide and only certified pharmacies can dispense pomalidomide in the Pomalidomide REMS.

In order to receive pomalidomide, all patients must be enrolled in the Pomalidomide REMS and agree to comply with the requirements of the Pomalidomide REMS. Information about pomalidomide and the Pomalidomide REMS can be obtained by visiting [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com), or calling the REMS Coordinating Center at **1-866-245-7925**.

# Key Points of the Pomalidomide REMS

## Prescribers

- The prescriber reviews the Prescribing Information for pomalidomide.
- The prescriber enrolls and becomes certified in the Pomalidomide REMS by completing the **Prescriber Enrollment Form** and submitting it to the Pomalidomide REMS.
- The prescriber counsels patients on the benefits and risks of pomalidomide therapy, including Boxed Warnings and the need to complete mandatory patient surveys with the Pomalidomide REMS using the information in the Medication Guide, the **Patient Guide** and the **Patient-Physician Agreement Form**.
- The prescriber provides contraception and emergency contraception counseling with each new prescription prior to and during pomalidomide treatment.
  - For males (adults and children): Counsel the patient on the barrier contraception requirements and emergency contraception using the **Patient Guide** and the **Emergency Contraception Brochure**, and provide a copy of the materials to the patient.
  - For females (adults and children) who can get pregnant: Counsel the patient on contraception requirements and emergency contraception using the **Patient Guide** and the **Emergency Contraception Brochure**, and provide a copy of the materials to the patient.
- The prescriber provides scheduled pregnancy testing for females who can get pregnant and verify negative pregnancy test results prior to writing a new prescription or subsequent prescription.
  - For females (adults and children) who can get pregnant: Assess the patient's pregnancy status by ordering and confirming a negative test result at the following timeframes:
    - Before treatment initiation (first prescription):
      - 10-14 days prior to initiation of pomalidomide therapy
      - Within 24 hours of the initial prescription
    - During treatment:
      - Every 4 weeks for female patients who can get pregnant with regular menstrual cycles
      - Every 2 weeks for female patients who can get pregnant with irregular menstrual cycles
- The prescriber enrolls each patient by completing the appropriate **Patient-Physician Agreement Form** and sends to the REMS Coordinating Center.

- The prescriber/patient completes applicable mandatory confidential surveys.
- The prescriber obtains authorization by contacting the REMS program and completing the prescriber survey to verify the patient's reproductive status, negative pregnancy test status, and completion of counseling. The prescriber must document the prescription authorization number and the patient's risk category on the prescription.
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions.
- The prescriber sends the pomalidomide prescription to a certified pharmacy.

## Pharmacies

- The pharmacy enrolls into the Pomalidomide REMS to become certified by completing the **Pharmacy Enrollment Form** and submitting it to the Pomalidomide REMS.
- The pharmacy reviews or completes the following: **Pharmacy Guide**, **Pharmacy Training**, and **Pharmacy Certification Quiz**.
- The certified pharmacy counsels the patient on the benefits and risks of pomalidomide, and safe-use requirements using the **Education and Counseling Checklist for Pharmacies**.
- The certified pharmacy verifies that a prescription authorization number and patient risk category is documented on each prescription.
- The certified pharmacy must obtain a confirmation number to dispense each prescription by contacting the REMS program to verify the prescriber is certified, the patient enrolled is not pregnant, and the prescriber's authorization number is valid.
- The certified pharmacy documents the confirmation number and the date it was obtained on the prescription.
- The certified pharmacy completes the **Education and Counseling Checklist for Pharmacies**.
- The certified pharmacy dispenses no more than a 28 days' supply of pomalidomide to the patient along with a Medication Guide, only if there are 7 days or less remaining on the existing prescription.

# Prescribing Pomalidomide Under the Pomalidomide REMS

## FEMALES

### Patient Counseling

Instruct your patients on why and how they and their partners should prevent pregnancy. Also inform them not to share the drug, not to donate blood, and about using 2 effective methods of contraception (at least one highly effective method and one effective method) at the same time. Patient should be instructed not to extensively handle or open pomalidomide capsules.

### Pregnancy Tests Only in Females

#### Who Can Get Pregnant

Conduct initial pregnancy test within 10-14 days of treatment initiation. Confirm the patient is not pregnant with a second pregnancy test within 24 hours prior to writing an initial prescription and verify a negative test result weekly during the first 4 weeks of use. During treatment, pregnancy testing should be repeated every 4 weeks if the patient has regular menses or is amenorrheic, or every 2 weeks if the patient has irregular menses.

### Enrollment

Both you and your patients must understand and agree to comply with the Pomalidomide REMS, including the pregnancy prevention steps. The applicable ***Patient-Physician Agreement Form*** must be signed by both patient and physician and submitted to the REMS Coordinating Center via fax (1-844-872-5446) or electronically at [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com).

### Complete Mandatory Confidential Survey

Your female patients need to complete a brief survey by phone or online. You will also need to complete a mandatory survey by phone or online. You must complete this survey every time a pomalidomide prescription is written. After your patient completes her survey, you will also be asked to complete a survey. Once you complete the survey you will then receive an authorization number to write the prescription. You must complete this survey to obtain a new authorization number every time a pomalidomide prescription is written. Female patients who can get pregnant and all female children must complete surveys monthly in order to obtain subsequent prescriptions. Adult female patients who cannot get pregnant must complete surveys every 6 months.

## MALES

### Patient Counseling

Instruct your patients on why and how they and their partners should prevent pregnancy. Also, inform them not to share the drug, not to donate blood, or sperm, and about appropriate contraceptive use. Patients should be instructed not to extensively handle or open pomalidomide capsules.

### Enrollment

Both you and your patients must understand and agree to comply with the Pomalidomide REMS, including the pregnancy prevention steps.

The applicable ***Patient-Physician Agreement Form*** must be signed by both patient and physician and submitted to the REMS Coordinating Center via fax (1-844-872-5446) or electronically [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com).

### Complete Mandatory Confidential Survey

Your male patients will need to complete a brief survey by phone or online. You will also need to complete a mandatory survey by phone or online, after which you will receive an authorization number. You must complete this survey to obtain a new authorization number every time a pomalidomide prescription is written. The *initial survey* is *not required* for male patients, but they must complete surveys monthly for subsequent prescriptions.

## Pomalidomide REMS Patient Enrollment

- Obtain, review, and complete the applicable **Patient-Physician Agreement Form** online by visiting [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) or submit the form via fax **1-844-872-5446**.
- Prescribers who do not have access to a computer will be provided with Pomalidomide REMS materials. For additional assistance, please contact the REMS Coordinating Center at **1-866-245-7925**.

### Help Ensure Timely Processing of Each Prescription: Fill Out Form as Directed

- The form must be completed and signed by both prescriber and patient.

#### Instructions for Female Patients

- Provide information on whether the patient has been in surgical menopause or natural menopause for at least 24 months.

#### Instructions for Minors

- If the patient is under 18 years of age, his or her legal guardian must read this material and agree to ensure compliance by signing and dating the form.

#### Instructions for Incompetent Adult Patients

- For an incompetent adult patient, an authorized representative must sign the **Patient-Physician Agreement Form**.
- An authorized representative is a caretaker authorized under applicable state law to consent to treatment on the incompetent patient's behalf.
- The authorized representative must read the material and agree to ensure compliance by signing and dating the form.
- If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the REMS Coordinating Center, along with the Patient-Physician Agreement Form.**
- This letter must contain the following: A statement that the incompetent patient lacks the capacity to complete the **Patient-Physician Agreement Form**, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the Pomalidomide REMS and is authorized to consent to treatment with pomalidomide on behalf of the patient.

### Send in Completed Forms

- Send the completed **Patient-Physician Agreement Form** to the REMS Coordinating Center via fax (**1-844-872-5446**) or electronically at [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com).
- You will receive confirmation electronically that the patient is enrolled.
- Once the **Patient-Physician Agreement Form** is received, both female patients and prescribers can take their surveys as required. Male patients do not take initial surveys.

**NOTE:** *If therapy with pomalidomide is discontinued for 12 consecutive months, the patient must enroll again in the Pomalidomide REMS. Follow the above procedures to re-enroll the patient.*

# Prescription Requirements

## All Patients

- Provide comprehensive counseling on the benefits and risks of therapy with pomalidomide, including risks described in the Boxed Warnings and the need to complete mandatory patient surveys with the Pomalidomide REMS using the [Patient Guide](#) and **Patient-Physician Agreement Form**.
- Patients must be counseled on the potential risks of birth defects, other side effects, and important precautions associated with pomalidomide.
- Provide counseling not to share pomalidomide, and not to donate blood during treatment (including dose interruptions) and for 4 weeks after receiving their last dose of pomalidomide, as well as counseling on appropriate contraceptive use, including emergency contraception.
- Provide patients with educational materials provided in the Pomalidomide REMS.
- Patients should be instructed to not extensively handle or open pomalidomide capsules.
- Instruct patients to return unused pomalidomide for disposal to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide.

## Female Patients

*Determine if female patient is able to get pregnant*

### Two Categories

1

#### Females Who Can Get Pregnant

All females who are menstruating, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females who cannot get pregnant category

2

#### Females Who Cannot Get Pregnant

Females who have been in natural menopause for at least 24 consecutive months, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating or show signs of puberty

## Females Who Can Get Pregnant

### Pregnancy Test Requirements

- Obtain a negative pregnancy test 10 to 14 days prior to writing an initial prescription for pomalidomide and again within 24 hours prior to writing an initial prescription for pomalidomide even if continuous abstinence is the chosen method of birth control.
  - The pregnancy test must be sensitive to at least 50 mIU/mL.
  - Pregnancy testing should be repeated weekly for at least the first 4 weeks, and then every 4 weeks if patient has regular menses, or every 2 weeks if irregular menses.

### Prescription Requirements

- If a patient misses her period or if there is any abnormality in menstrual bleeding, pomalidomide should be discontinued immediately. Obtain a pregnancy test and counsel the patient.
- **If pregnancy does occur during treatment, pomalidomide must be immediately discontinued.** Any suspected embryo-fetal exposure to pomalidomide must be reported immediately to the FDA via the MedWatch number at **1-800-FDA-1088** and also to the REMS Coordinating Center at **1-866-245-7925**. The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling.
- The patient must not breastfeed a baby while being treated with pomalidomide.

# Patient Counseling on Contraception Requirements

## Contraception Requirements

- Female patients who can get pregnant must either completely abstain from heterosexual sexual contact or must use 2 effective methods of contraception (at least one highly effective method and one effective method) at the same time.
- The 2 effective contraceptive methods include using at the same time at least 1 highly effective method and at least 1 additional method of birth control every time they have sex with a male.
- The 2 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.

## Effective Methods of Birth Control to Use at the Same Time

Highly effective birth control methods	Additional effective birth control methods
<ul style="list-style-type: none"><li>• Intrauterine device (IUD)</li><li>• Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)</li><li>• Tubal ligation (having your tubes tied)</li><li>• Partner's vasectomy (tying of the tubes to prevent the passing of sperm)</li></ul>	<ul style="list-style-type: none"><li>• Male latex or synthetic condom</li><li>• Diaphragm</li><li>• Cervical cap</li></ul>

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

- **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\*
- 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 stopping therapy.

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

## Females Who Cannot Get Pregnant

- The patient must confirm that she is currently not pregnant, nor of reproductive potential as she has been in natural menopause for at least 24 months, or had a hysterectomy and/or bilateral oophorectomy.
- The parent or guardian must confirm that a pre-pubertal female child is not pregnant, nor is of reproductive potential as **menstruation has not yet begun**, the child does not show signs of puberty and/or the child will not be engaging in heterosexual sexual contact for at least 4 weeks before pomalidomide therapy, during therapy, during dose interruptions, and for at least 4 weeks after stopping therapy.

## Male Patients

- Male patients must be instructed to use a latex or synthetic condom every time they have sexual intercourse with a female who can get pregnant, even if they have undergone a successful vasectomy. The risk to the developing baby from the semen of male patients taking pomalidomide therapy is unknown.
- Male patients must be instructed not to donate sperm during treatment (including dose interruptions) and for 4 weeks after their last dose of pomalidomide.

## Initial Mandatory Confidential Survey

### Females

Instruct the female patient to complete a brief initial mandatory confidential survey by visiting [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com), or by calling the REMS Coordinating Center at **1-866-245-7925**.

### Males

Males do not need to take the initial survey.

### Prescribers

- Prescriber will complete a brief mandatory confidential survey by visiting [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com), or calling the REMS Coordinating Center at **1-866-245-7925**, for **every patient** before each prescription is written. Be prepared to enter some of the following information:
  - Prescriber's identification number
  - Patient's identification number
  - Date and result of patient's pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
  - Average daily dose
  - Total number of days' supply (cannot exceed 28 days)
- An authorization number will be issued upon completion of the survey. Authorization numbers are valid for 7 days from the date of the last pregnancy test for females who can get pregnant and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.

### **Additional Information for the Prescriber**

- Prescribers must send the prescription to a Pomalidomide REMS certified pharmacy. To locate a certified pharmacy, please visit [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com).
- Prescribe no more than 4 weeks (28 days) of therapy, with no automatic refills or telephone prescriptions.

## Subsequent Prescription Requirements

The prescriber must complete a brief mandatory, confidential survey to obtain a new authorization number **every time** a prescription for pomalidomide is written.

No automatic refills or telephone prescriptions are permitted.

### **Female Patients**

- Provide counseling as outlined in the "Female Patients" section on page 4.
- Follow pregnancy test requirements as outlined in the "Pregnancy Test Requirements" section on page 6.
- Female patients must complete a brief mandatory confidential survey according to the following schedule:
  - Before prescription is obtained
  - Monthly
    - Adult who can get pregnant
    - All female children
  - Every 6 months
    - Adult females who cannot get pregnant

### **Male Patients**

- Provide patient counseling as outlined in the "Male patients" section on page 4.
- Male patients must complete a brief mandatory confidential survey once a month.
  - Males do not complete an initial survey.

## After the Last Dose of Pomalidomide

After patients have stopped taking pomalidomide, they must do the following:

### All Patients

- Must not share pomalidomide
- Must return any unused pomalidomide capsules for disposal to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide
- Must not donate blood for 4 weeks after stopping pomalidomide

### Females Who Can Get Pregnant

- Must not get pregnant for at least 4 weeks after stopping pomalidomide by using 2 effective methods of contraception (at least one highly effective method and one effective method) each time engaging in sexual activity with a male

### Male Patients

- Must use a latex or synthetic condom each time when engaging in sexual activity for 4 weeks after stopping pomalidomide, even if they have undergone a successful vasectomy
- Must not donate sperm for 4 weeks after stopping pomalidomide

## Reporting Adverse Events

Adverse drug experiences that are suspected to be associated with the use of pomalidomide and any suspected pregnancy occurring during the treatment with pomalidomide may be reported to the Pomalidomide REMS [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com) or via the REMS Coordinating Center at **1-866-245-7925**.

You may also report to the FDA via <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>, phone: 1-800-FDA-1088, Fax: 1-800-FDA-0178 or mail MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787.

For more information about pomalidomide and the Pomalidomide REMS, please visit [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com), or call the REMS Coordinating Center at **1-866-245-7925**.

# POMALIDOMIDE RISK EVALUATION AND MITIGATION STRATEGY (REMS)

## Education and Prescribing Safety Kit

### About Pomalidomide

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**This is not a comprehensive description of risks associated with the use of pomalidomide. Please see Prescribing Information<sup>1</sup>, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.**

### Prescriber Quick Reference Guide

1. The prescriber provides comprehensive counseling.
  2. The prescriber verifies negative pregnancy test for all female patients of reproductive potential.
  3. The prescriber completes the **Patient-Physician Agreement Form** with each patient and sends to REMS Coordinating Center.
  4. Female patients complete initial mandatory confidential survey by:
    - Visiting [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com)
    - Calling the REMS Coordinating Center at 1-866-245-7925Male patients do not need to complete the initial survey.
- All patients must complete subsequent mandatory confidential surveys as outlined in the **Prescriber Guide**.
5. The prescriber completes mandatory confidential survey and receives authorization number by:
    - Visiting [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com)
    - Calling the REMS Coordinating Center at 1-866-245-7925
  6. The prescriber writes the pomalidomide prescription and includes the authorization number and patient risk category.
  7. The prescriber sends prescription to a certified pharmacy.

This flow sheet should be used only as a quick reference and only after reviewing all of the Pomalidomide REMS procedures.

**Pomalidomide is only available under a restricted distribution program, the Pomalidomide REMS**

<sup>1</sup> Please note, the enclosed materials include Prescribing Information from each generic pomalidomide manufacturers participating in the Pomalidomide REMS.

POMALIDOMIDE RISK EVALUATION AND MITIGATION STRATEGEMENTSERATION  
(REMS)

# Pharmacy Guide

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2	Guidelines for Ordering, Counseling, and Dispensing Pomalidomide
4	<a href="#">Education and Counseling Checklist for Pharmacies</a>
5	Rules for Dispensing and Shipping
6	Adverse Drug Experience Reporting Procedure for Healthcare Professionals

## Important Information About the Pomalidomide REMS

- Pomalidomide is contraindicated in pregnant females or females capable of becoming pregnant. Females who can get pregnant may be treated with pomalidomide if they take adequate precautions to avoid pregnancy.
- To avoid embryo-fetal exposure, pomalidomide is only available through a restricted distribution program called the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS).
- Only certified prescribers can prescribe pomalidomide and only certified pharmacies can dispense pomalidomide in the Pomalidomide REMS.
- Dispensing pharmacists must be educated on the Pomalidomide REMS and on dispensing procedures for pomalidomide.
- Information about pomalidomide and the Pomalidomide REMS can be obtained by visiting [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com), or by calling the REMS Coordinating Center toll-free at 1-866-245-7925.

## Guidelines for Ordering, Counseling, and Dispensing Pomalidomide

Dispensing pharmacies must be certified in the Pomalidomide REMS and must be educated in the following dispensing procedures.

### Step 1. Review Incoming Pomalidomide Prescriptions

- A. Only accept prescriptions with an authorization number and patient risk category written on them
- B. Make sure the prescription is signed and dated
- C. Confirm the prescription is written for a 4-week (28-day) supply or less
- D. For subsequent prescriptions, verify there are 7 days or less remaining of therapy on the existing prescription

### Step 2. Counsel Patient

- A. Make sure a **certified Pomalidomide REMS** counselor counsels the patient.
  - Pomalidomide REMS counselors must:
    1. Be licensed healthcare professionals
    2. Complete the Pomalidomide REMS training as provided by the certified pharmacy Authorized Representative
    3. Educate patient by telephone or in person before treatment can be dispensed
    4. Understand and counsel patients on the potential for birth defects or death to an unborn baby
    5. Counsel patients on possible side effects
  - Other pharmacy staff involved in dispensing treatment must:
    1. Be educated on the guidelines for dispensing
- B. Complete the corresponding section (based on the patient risk category) of the ***Education and Counseling Checklist for Pharmacies*** and ensure the form is signed and dated. Ensure the appropriate boxes are checked off. Retain a copy of the checklist and record of the associated prescription.
- C. If the patient mentions adverse drug experiences that are suspected to be associated with the use of pomalidomide and any suspected pregnancy occurring during the treatment with pomalidomide, make sure to document these experiences and notify the Pomalidomide REMS.
- D. Report adverse drug experiences that are suspected to be associated with the use of pomalidomide to the Pomalidomide REMS within 24 hours.

# Guidelines for Ordering, Counseling, and Dispensing Pomalidomide

## Step 3. Obtain a Confirmation Number from the Pomalidomide REMS

- A. Prior to each prescription, ensure the patient and prescriber are enrolled in the Pomalidomide REMS by obtaining a confirmation number from the REMS Coordinating Center (**1-866-245-7925**) or visiting the Pomalidomide REMS website (**www.PomalidomideREMSProgram.com**).
- B. The pharmacy will confirm that both the patient and the prescriber have both completed the mandatory confidential survey prior to each prescription and a valid authorization number was received. Once there is confirmation that all REMS requirements have been met, the pharmacy will obtain a confirmation number from the Pomalidomide REMS.
  - Authorization numbers are valid for 7 days from the date of last pregnancy test for females who can get pregnant and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
  - Confirmation numbers can be obtained:
    1. Search Certified Prescriber (name and National Provider Identifier (NPI))
    2. Search Enrolled Patient (name and date of birth)
    3. Enter Authorization Number
    4. Enter Number of Capsules and Milligram Strength
    5. Generate Confirmation Number
    6. Document Confirmation Number
- C. Faxed prescriptions are permissible depending on state laws.
- D. If you do not obtain a confirmation number after confirming that all REMS requirements have been met, do not dispense pomalidomide.

## Step 4. Dispensing

- A. No Refills. A new prescription is required for each dispense. **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription.**
- B. Ensure the confirmation number has not expired, i.e., dispense within 24 hours from confirmation number receipt. If more than 24 hours have elapsed, **you must generate a new confirmation number**. For female patients who can get pregnant, ship the same day or hand to the patient within 24 hours.
- C. Dispense each prescription with a Medication Guide and maintain a record on acceptable documentation.
  - **Acceptable documentation examples:**
    1. Signed **Education and Counseling Checklist for Pharmacies** (if counseling pharmacist and dispensing pharmacist are the same)
    2. Pharmacy log
- D. Document the dispense date and maintain a record on acceptable documentation.
  - **Acceptable documentation examples:**
    1. Shipping receipt
    2. Pharmacy dispensing log
- E. Dispense no more than a 4-week (28-day) supply. A new prescription is required for each dispense. No automatic refills or telephone prescriptions are permitted.
- F. A signature is required for all shipments and dispenses if picked up by patient.
- G. Pharmacies must submit records of pomalidomide dispensing to the Pomalidomide REMS.

## Step 5. Perform drug accountability

- A. Pharmacy shall keep an inventory log for pomalidomide, by strength, reflecting its on-hand inventory at all times.
- B. Do not transfer pomalidomide to another pharmacy without permission from the Pomalidomide REMS.
- C. Accept unused pomalidomide (previously dispensed) from a patient or patient caregiver.
- D. Return unused product from the patient or the prescriber to the Pomalidomide REMS.

## Pomalidomide Risk Evaluation and Mitigation Strategy (REMS) Education and Counseling Checklist for Pharmacies

### *Ensure your patients know the risks*

Before you are able to fill a prescription for pomalidomide, a checklist for each patient must be completed based on the patient risk category. When completing the checklist, be sure all the appropriate boxes are checked off (✓) and the form is signed and dated. All boxes and spaces must be marked or filled in during counseling with the patient for every prescription. Retain a copy of the checklist and record of the associated prescription.

#### **Be prepared to provide the following information for each checklist:**

- Pharmacy Name
- Pharmacy Address (including City, State, ZIP Code)
- Counselor Name
- Work Phone Number
- Extension
- Patient Name
- Patient Date of Birth



## Rules for Dispensing and Shipping

### *Making sure before you release pomalidomide*

**DO NOT DISPENSE OR SHIP POMALIDOMIDE TO A PATIENT UNLESS ALL THE FOLLOWING ARE DONE:**

- Prescription has an authorization number and patient risk category written on it.
- You have obtained a confirmation number and a confirmation date.
- You are shipping the product within 24 hours of obtaining the confirmation number. For females who can get pregnant, the product must be shipped the same day the confirmation number is obtained.
- The Medication Guide is included with the prescription.
- You confirm the prescription is no more than a 4-week (28-day) supply and there are 7 days or less remaining on the existing pomalidomide prescription.

**For further information about pomalidomide, please refer to the Prescribing Information, enclosed.**

## Adverse Drug Experience Reporting Procedure for Healthcare Professionals

Please report adverse drug experiences that are suspected to be associated with the use of pomalidomide and any suspected pregnancy occurring during the treatment with pomalidomide to the Pomalidomide REMS using any of the following methods.

### REPORTING TO POMALIDOMIDE REMS

- Online: [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com)
- Email: [drugsafety@UBC.com](mailto:drugsafety@UBC.com)
- Telephone: **1-866-245-7625**
- Fax: **1-844-872-5446**
- Mail to: **2083 Pinecrest Dr, Morgantown, WV 26505**

### REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of pomalidomide and any suspected pregnancy occurring during the treatment with pomalidomide may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online at: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>
- Telephone/Fax or Mail: **1-800-FDA-1088** Fax: **1-800-FDA-0178** MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787



For more information about pomalidomide and the Pomalidomide REMS,  
please visit [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com),  
or call the REMS Coordinating Center at 1-866-245-7925.

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

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



# Pomalidomide REMS Pharmacy Training

## Table of Contents

- **Section 1:** What is a REMS?
- **Section 2:** Program Requirements for Patients and Prescribers
- **Section 3:** Program Requirements for Pharmacies
- **Section 4:** Guidelines for Counseling
- **Section 5:** Guidelines for Dispensing



# Pomalidomide REMS Pharmacy Training

Section 1: What is a REMS?

## In this section

- What is a REMS?
- Pharmacy Staff Knowledge Check

## What is a REMS?

- REMS stands for Risk Evaluation and Mitigation Strategies
- REMS programs are mandated by the US Food and Drug Administration (FDA)
- According to the FDA, a REMS program is:
  - A strategy to manage a known or potential serious risk associated with a drug or biological product
- The FDA determines if a REMS program is necessary to ensure that the benefits of the drug outweigh the risks

## Pomalidomide REMS

- **Risk:** If pomalidomide is used during pregnancy, it can cause serious birth defects or embryo-fetal death
- The goal of the Pomalidomide REMS is:
  - To prevent the risk of embryo-fetal exposure to pomalidomide
  - To inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for pomalidomide

## Pharmacy Staff Knowledge Check

- REMS stands for Risk Evaluation and Mitigation Strategies.
  - A. True
  - B. False

# Pharmacy Staff Knowledge Check

- REMS stands for Risk Evaluation and Mitigation Strategies.
  - A. True
  - B. False

**Correct Answer: A. True**

- REMS stands for **Risk Evaluation and Mitigation Strategies**
- A REMS is a strategy to manage a known or potential serious risk associated with a drug or biological product

## Pharmacy Staff Knowledge Check ( continued)

- Who mandates REMS programs?
  - A. The Pomalidomide REMS Manufacturers
  - B. The Food and Drug Administration (FDA)
  - C. The Environmental Protection Agency (EPA)

## Pharmacy Staff Knowledge Check ( continued)

- Who mandates REMS programs?
  - A. The Pomalidomide REMS Manufacturers
  - B. The FDA
  - C. The EPA

**Correct Answer: B. FDA**

- REMS programs are mandated by the FDA
- The FDA determines if a REMS program is necessary to ensure that the benefits of the drug outweigh the risks

## Pharmacy Staff Knowledge Check ( continued)

- The Pomalidomide REMS is mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for pomalidomide.
  - A. True
  - B. False

## Pharmacy Staff Knowledge Check ( continued)

- The Pomalidomide REMS is mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for pomalidomide.
  - A. True
  - B. False

**Correct Answer: A. True**

- The goals of the Pomalidomide REMS are:
  - To prevent the risk of embryo-fetal exposure to these treatments
  - To inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for pomalidomide



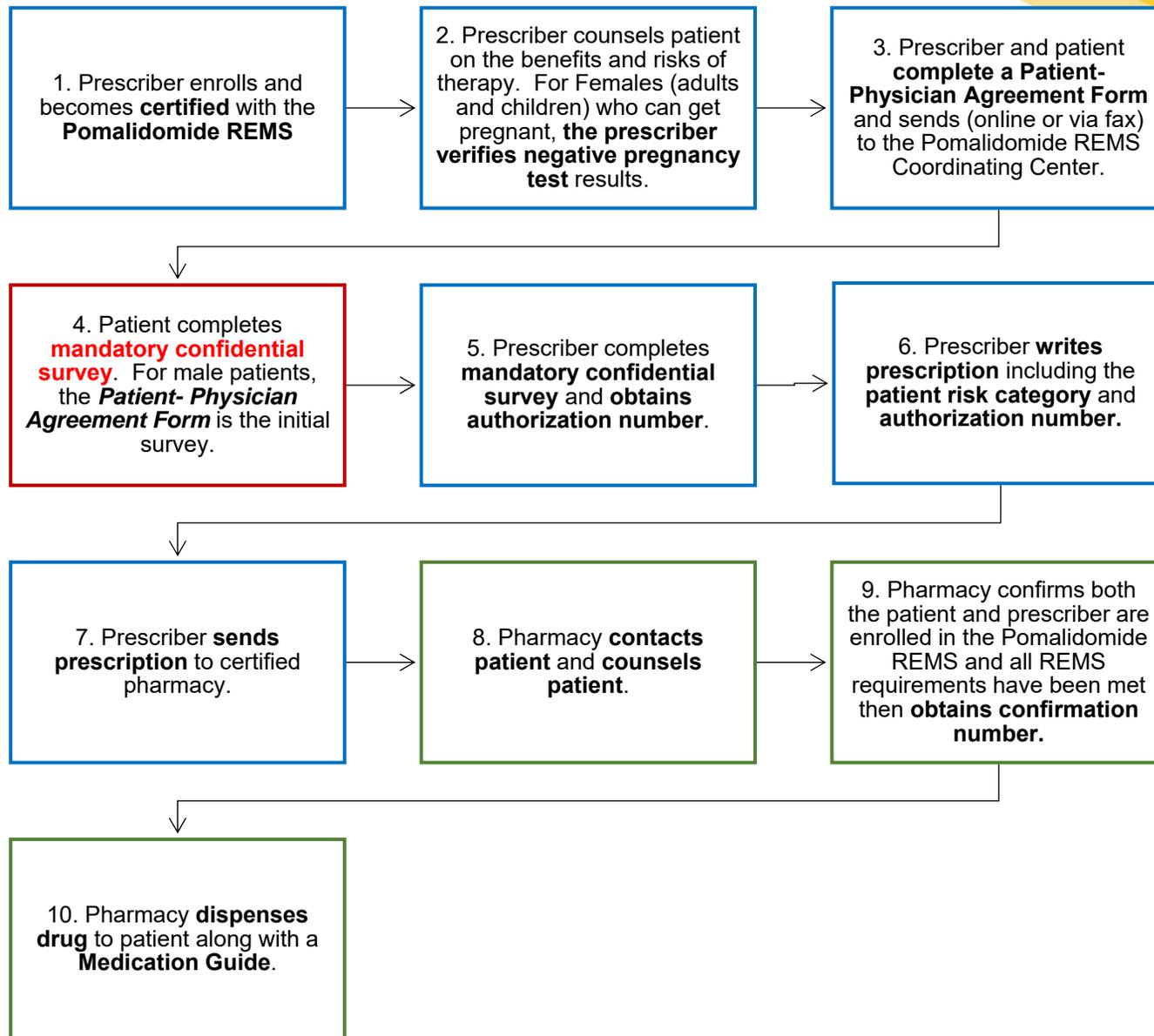
# Pomalidomide REMS Pharmacy Training

Section 2: Program Requirements  
for Patients and Prescribers

## In this section

- Program overview
- Certification and enrollment requirements for prescribers and patients
- Patient risk categories
- Contraception requirements
- Pregnancy test requirements
- Mandatory confidential surveys
- Pharmacy staff knowledge check

# Pomalidomide REMS Program Overview



## Certification and enrollment requirements for prescribers and patients

- Prescribers must be certified with the Pomalidomide REMS in order to prescribe pomalidomide for a patient
  - Prescribers must complete the Pomalidomide REMS **Prescriber Enrollment Form** and agree to comply with the program requirements
- Prescribers are required to enroll patients in the Pomalidomide REMS before starting a patient on a therapy
  - Patients must enroll in the Pomalidomide REMS by completing the **Patient-Physician Agreement Form** and agree to comply with the program requirements

## Patient risk categories

- There are 6 different patient risk categories for patients enrolled in Pomalidomide REMS:
  1. Adult female who can get pregnant
  2. Female child who can get pregnant
  3. Adult female who cannot get pregnant
  4. Female child who cannot get pregnant
  5. Adult male
  6. Male child

## Definition of females who can get pregnant

- **Females (adults and children) who can get pregnant** include all females who:
  - Are menstruating
  - Are amenorrheic from previous medical treatments
  - Are under 50 years of age
  - Are perimenopausal
  - Do not qualify for the females not of reproductive potential category
- The risk categories for **females who can get pregnant** are:
  - Adult Female who can get pregnant
  - Female child who can get pregnant

## Definition of females who cannot get pregnant

- **Females who cannot get pregnant** include females who:
  - Have been in natural menopause for at least 24 consecutive months
  - Have had a hysterectomy and/or bilateral oophorectomy
  - Have not started menstruating or shown signs of puberty
- The risk categories for **females who cannot get pregnant** are:
  - Adult female who cannot get pregnant
  - Female child who cannot get pregnant

## Definition of males

- **Males** include adults and children (under 18 years of age)
- The risk categories for **males** are:
  - Adult Male
  - Male Child

## Contraception requirements: Females who can get pregnant

- Female patients (adults and children) who can get pregnant must either completely abstain from heterosexual sexual contact or must use 2 effective methods of contraception (at least one highly effective method and one effective method) at the same time
- The 2 effective contraceptive methods include using at the same time **at least 1 highly effective method** and **at least 1 additional method** of birth control every time they have sex with a male
- The 2 effective contraceptive methods must be started at least 4 weeks before therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

### Highly Effective Methods

Tubal ligation

Intrauterine device (IUD)  
Hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants)

Partner's vasectomy

+

### Additional Effective Methods

Male latex or synthetic condom

Diaphragm

Cervical cap

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

## Contraception requirements: Females who can get pregnant (continued)

- **Unacceptable contraception methods:**
  - 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

## Contraception requirements: Males

- Male patients must use a latex or synthetic condom:
  - Every time they have sexual intercourse with a female of reproductive potential even if they have undergone a successful vasectomy
  - During therapy (including dose interruptions)
  - For 4 weeks after discontinuation of therapy

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

## Pregnancy test requirements

- For females (adults and children) who can get pregnant: the prescriber must assess the patient's pregnancy status by ordering and confirming a negative test result at the following timeframes:
  - Before treatment initiation (first prescription):
    - 10-14 days prior to initiation of pomalidomide therapy
    - Within 24 hours of the initial prescription
  - During treatment:
    - Weekly during the first 4 weeks of use
    - Thereafter,
      - Every 4 weeks for female patients who can get pregnant with regular menstrual cycles
      - Every 2 weeks for female patients who can get pregnant with irregular menstrual cycles
- The pregnancy test must be sensitive to at least 50 mIU/mL

## Pregnancy test requirements (continued)

### If pregnancy does occur:

- Treatment must be **immediately** discontinued
- Any suspected embryo-fetal exposure must be reported **immediately** to the REMS Coordinating Center and reported to the FDA
  - Pomalidomide REMS Coordinating Center: 1-866-245-7925
  - FDA MedWatch number: 1-800-FDA-1088
- The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling

## Mandatory confidential surveys

- All patients must complete brief mandatory confidential surveys in order to obtain treatment
- Surveys can be completed via [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com), or by calling the REMS Coordinating Center at 1-866-245-7925

### Patient Mandatory Confidential Survey Schedule for Adults and Children

Risk Category	Initial Prescription	Subsequent Prescriptions
Females who can get pregnant	Complete appropriate survey	Monthly survey
Females who cannot get pregnant	Complete appropriate survey	Child: Monthly survey Adult: Survey every 6 months
Males	Do not need to take initial survey	Monthly survey

## Pharmacy staff knowledge check

- How many patient risk categories are there in the Pomalidomide REMS?
  - A. 3
  - B. 5
  - C. 6

## Pharmacy staff knowledge check

- How many patient risk categories are there in the Pomalidomide REMS?
  - A. 3
  - B. 5
  - C. 6

**Correct Answer: C. 6**

<b>Pomalidomide REMS patient risk categories</b>	
<b>Adult</b>	<b>Child (under 18)</b>
Adult female who can get pregnant	Female child who can get pregnant
Adult female who cannot get pregnant	Female child who cannot get pregnant
Adult male	Male child

## Pharmacy staff knowledge check (continued)

- For the Pomalidomide REMS, female patients (adults and children) who can get pregnant must take:
  - A. Only one pregnancy test 10-14 days before first prescription
  - B. Only one pregnancy test within 24 hours before first prescription
  - C. Two pregnancy test: 10-14 days before and within 24 hours prior to first prescription

## Pharmacy staff knowledge check (continued)

- For the Pomalidomide REMS, female patients (adults and children) who can get pregnant must take:
  - A. Only one pregnancy test 10-14 days before first prescription
  - B. Only one pregnancy test within 24 hours before first prescription
  - C. Two pregnancy test: 10-14 days before and within 24 hours prior to first prescription

**Correct Answer:**

**C. Two pregnancy test: 10-14 days before  
and within 24 hours prior to first prescription**

- Prescribers must obtain 2 negative pregnancy tests before the first prescription for females who can get pregnant:
  - 10 to 14 days before an initial prescription
  - Within 24 hours before an initial prescription

## Pharmacy staff knowledge check (continued)

- Which is a **highly effective** method of contraception?
  - A. Male latex or synthetic condom
  - B. IUD
  - C. Female condom

## Pharmacy staff knowledge check (continued)

- Which is a **highly effective** method of contraception?
  - A. Male latex or synthetic condom
  - B. IUD
  - C. Female condom

**Correct Answer: B. IUD**

Highly Effective Methods	Additional Effective Methods
Tubal ligation	Male latex or synthetic condom
Intrauterine device (IUD)	Diaphragm
Hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Cervical cap
Partner's vasectomy	



# Pomalidomide REMS Pharmacy Training

Section 3: Program Requirements for  
Pharmacies

## In this section

- Training and certification requirements
- Pharmacy compliance
- Pharmacy staff knowledge check

## Training and certification requirements

- Pomalidomide REMS counselors must:
  - Be licensed healthcare professionals
  - Complete the Pomalidomide REMS training **annually** and pass certification exam **with 100% accuracy**
  - Educate patient by telephone or in person before treatment can be dispensed
  - Understand and counsel patients on the potential for birth defects or death to an unborn baby
  - Counsel patients on possible side effects
- Other pharmacy staff involved in dispensing treatment must:
  - Be educated on the guidelines for dispensing

## Pharmacy compliance

- Pharmacy manager responsibilities
  - Educate all staff regarding dispensing guidelines
  - Includes floater pharmacists, pharmacy technicians, or anyone else handling the product
  - Complete and return all documentation that pertains to non-compliance

**Did you know?** Pharmacy managers can call the REMS Coordinating Center at **1-866-245-7925** with questions.

## Pharmacy compliance (continued)

- Pharmacy deviations
  - The pharmacy will be required to investigate and correct conditions that lead to deviations from Pomalidomide REMS
  - The Pomalidomide REMS Coordinating Center will work with the pharmacy to implement appropriate corrective actions and a timeframe for those actions
  - If corrective actions are not successful, the Pomalidomide REMS may take additional action, up to and including deactivation of the pharmacy

## Pharmacy compliance (continued)

- A High Risk Deviation is:
  - Any action taken by the pharmacy that is inconsistent or non-compliant with the Pomalidomide REMS that increases the risk of embryo-fetal exposure
  - Any action that occurs on a consistent basis that shows a pharmacy's negligent or willful disregard to the Pomalidomide REMS program requirements
  - For any additional occurrence of a High Risk Deviation beyond 2 High Risk Deviations, the pharmacy may be deactivated and no longer permitted to dispense product

## Pharmacy staff knowledge check

- Pomalidomide REMS program certified counselors must complete the training:
  - A. Annually
  - B. Every 6 months
  - C. Every 2 years

## Pharmacy staff knowledge check

- Pomalidomide REMS program certified counselors must complete the training:
  - A. Annually
  - B. Every 6 months
  - C. Every 2 years

**Correct Answer: A. Annually**

- Counselors must complete training annually

## Pharmacy staff knowledge check (continued)

- All counselors must pass the certification test with an accuracy of:
  - A. 100%
  - B. 90%
  - C. 95%

## Pharmacy staff knowledge check (continued)

- All counselors must pass the certification test with an accuracy of:
  - A. 100%
  - B. 90%
  - C. 95%

**Correct Answer: A. 100%**

- Counselors must pass the certification exam with 100% accuracy

## Pharmacy staff knowledge check (continued)

- The Pomalidomide REMS may deactivate pharmacies for deviations.
  - A. True
  - B. False

## Pharmacy staff knowledge check (continued)

- The Pomalidomide REMS may deactivate pharmacies for deviations.
  - A. True
  - B. False

**Correct Answer: A. True**

- The pharmacy will be required to investigate and correct conditions that lead to deviations from the Pomalidomide REMS
- If corrective actions are not successful, the Pomalidomide REMS may take additional action, up to and including deactivation of the pharmacy



# Pomalidomide REMS Pharmacy Training

## Section 4: Guidelines for Counseling

## In this section

- Counseling for female patients who can get pregnant
- Counseling for female patients who cannot get pregnant
- Counseling for male patients
- Additional counseling for all patients taking pomalidomide
- Pharmacy staff knowledge check

### POMALIDOMIDE REMS

#### Education and Counseling Checklist for Pharmacies

PHARMACY INFORMATION			
Pharmacy Name:			
Pharmacy Address:	City:	State:	ZIP Code:
Counselor Name:		Work Phone Number:	
PATIENT INFORMATION			
Patient Name:		Date of Birth:	
REMS CONFIRMATION			
Prescription Confirmation Number:		Confirmation Date:	
Patient Risk Category: <input type="checkbox"/> Adult Female Who Can Get Pregnant <input type="checkbox"/> Female Child Who Can Get Pregnant <input type="checkbox"/> Adult Male Who Can Not Get Pregnant <input type="checkbox"/> Male Child <input type="checkbox"/> Female Child Who Can Not Get Pregnant			
Confirmation Date:		Confirmation Prescriber is Certified, Patient is Enrolled and Not Pregnant (if applicable) and the Confirmation Number Provided by the Prescriber is Valid. <input type="checkbox"/> Yes <input type="checkbox"/> No	
Authorization Code:			
Checklist for Female Patients of Reproductive Potential			
<input type="checkbox"/> 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:			
<input type="checkbox"/> Potential embryo-fetal toxicity			
<input type="checkbox"/> Not taking pomalidomide if pregnant or breastfeeding			
<input type="checkbox"/> Using at the same time at least 1 highly effective method—tubal ligation, 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			
<input type="checkbox"/> 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			
<input type="checkbox"/> 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).			
<input type="checkbox"/> 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			
<input type="checkbox"/> 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			
<input type="checkbox"/> Possible side effects include deep vein thrombosis, pulmonary embolism, myocardial infarction and stroke			
<input type="checkbox"/> Not sharing pomalidomide capsules with anyone- especially with females who can get pregnant			
<input type="checkbox"/> Not donating blood while taking pomalidomide (including dose interruptions) and for 4 weeks after stopping pomalidomide			
<input type="checkbox"/> Not breaking, chewing, or opening pomalidomide capsules			
<input type="checkbox"/> Instructions on pomalidomide dose and administration			
Milligram (mg) Strength: _____		Number of Capsules Dispensed: _____	
FEMALE CHILDREN (<18 YEARS OF AGE):			
<input type="checkbox"/> Parent or legal guardian must have read the Pomalidomide REMS educational material and agreed to ensure compliance			

The sequence of this section is based on the [Education and Counseling Checklist for Pharmacies](#).

**Remember to fill out this checklist for every patient for every prescription.**

## Counseling for females who can get pregnant

- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

### **COUNSEL ADULTS AND CHILDREN ON:**

- Potential embryo-fetal toxicity
- Not taking treatment if pregnant or breastfeeding
- Using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time they have sex with a male**, or abstaining from sex with a male
  - **Highly effective** methods of contraception: Tubal ligation, intrauterine device (IUD), hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy
  - **Additional effective** methods of contraception: Male latex or synthetic condom, diaphragm, or cervical cap

## Counseling for females who can get pregnant (continued)

### **COUNSEL ADULTS AND CHILDREN ON:**

- 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
  - Cervical shield (a cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception)

## Counseling for females who can get pregnant (continued)

- **COUNSEL ADULTS AND CHILDREN ON:**
  - 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 treatment
    - During treatment
    - During dose interruptions
    - For at least 4 weeks after stopping treatment
    - **Every time they have sex with a male**, or abstaining from sex with a male

## Counseling for females who can get pregnant (continued)

- **COUNSEL ADULTS AND CHILDREN ON:**
  - Obtaining a pregnancy test—performed by their healthcare provider during the following timeframes:
    - Before treatment initiation (first prescription):
      - 10-14 days prior to initiation of pomalidomide therapy
      - Within 24 hours of the initial prescription
    - During treatment:
      - Weekly during the first 4 weeks of use
      - Thereafter,
        - Every 4 weeks for female patients who can get pregnant with regular menstrual cycles
        - Every 2 weeks for female patients who can get pregnant with irregular menstrual cycles
  - The need to stop treatment 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

# Counseling for females who can get pregnant (continued)

## COUNSEL ADULTS AND CHILDREN ON:

- Not sharing capsules with anyone
- Not donating blood during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Keeping pomalidomide prescription out of the reach of children
- Instructions on dose and administration
  - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist
- Returning any unused pomalidomide capsules for disposal to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide.

## FOR FEMALE CHILDREN (<18 YEARS OF AGE):

- Parent or legal guardian must have read the Pomalidomide REMS education material and agreed to ensure compliance
- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

## Counseling for females who cannot get pregnant

### **COUNSEL ADULTS AND CHILDREN ON:**

- Not sharing capsules with anyone
- Not donating blood during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Keeping pomalidomide prescription out of the reach of children
- Instructions on dose and administration
  - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist
- Returning any unused pomalidomide capsules for disposal to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide.

## Counseling for females who cannot get pregnant (continued)

- **FOR FEMALE CHILDREN (<18 YEARS OF AGE):**
- Parent or legal guardian must have read the Pomalidomide REMS education material and agreed to ensure compliance
- Parent or legal guardian must inform the child's doctor when the child begins menses or shows signs of puberty

## Counseling for male patients

- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

### **COUNSEL 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 they have undergone a successful vasectomy
- Female partners of males receiving treatment must call their healthcare provider right away if they get pregnant

## Counseling for male patients (continued)

### **COUNSEL ADULTS AND CHILDREN ON:**

- Not sharing capsules with anyone
- Not donating blood or sperm during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Keeping pomalidomide prescription out of the reach of children
- Instructions on dose and administration
  - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist
- Returning any unused pomalidomide capsules for disposal to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide.

### **FOR MALE CHILDREN (<18 YEARS OF AGE):**

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

## Additional counseling for all patients taking pomalidomide

### **COUNSEL ADULTS AND CHILDREN ON:**

- Possible side effects include deep vein thrombosis, pulmonary embolism, myocardial infarction and stroke

## Pharmacy staff knowledge check

- Which of these is **not** something patients need to be counseled on?
  - A. Not sharing capsules
  - B. Not breaking, chewing, or opening capsules
  - C. Wearing gloves while taking capsules

## Pharmacy staff knowledge check

- Which of these is **not** something patients need to be counseled on?
  - A. Not sharing capsules
  - B. Not breaking, chewing, or opening capsules
  - C. Wearing gloves while taking capsules

**Correct Answer: C. Wearing gloves while taking capsules.**

- Patients must be counseled on:
  - Not sharing capsules with anyone
  - Not breaking, chewing, or opening capsules
  - Keeping pomalidomide prescription out of the reach of children
  - Not donating blood while taking pomalidomide, during breaks (dose interruptions), and for 4 weeks after stopping pomalidomide
  - Returning any unused pomalidomide capsules for disposal to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide

## Pharmacy staff knowledge check (continued)

- Females who can get pregnant must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control for 4 weeks after stopping treatment.
  - A. True
  - B. False

## Pharmacy staff knowledge check (continued)

- Females who can get pregnant must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control for 4 weeks after stopping treatment.
  - A. True
  - B. False

**Correct Answer: A. True**

- Females who can get pregnant must continue 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 treatment
  - During treatment
  - During dose interruptions
  - For at least 4 weeks after stopping treatment
  - **Every time they have sex with a male**, or abstaining from sex with a male

## Pharmacy staff knowledge check (continued)

- All patients must receive a **Medication Guide** along with their prescription.
  - A. True
  - B. False

## Pharmacy staff knowledge check (continued)

- All patients must receive a **Medication Guide** along with their prescription.
  - A. True
  - B. False

**Correct Answer: A. True**

- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription



# Pomalidomide REMS Pharmacy Training

Section 5: Guidelines for Dispensing

## In this section

- Pharmacy and prescription requirements
- Dispensing guidelines
- Steps for dispensing
- Pharmacy staff knowledge check

## Pharmacy and prescription requirements

- Dispensing pharmacies **must be certified in the Pomalidomide REMS** by completing the ***Pharmacy Enrollment Form*** and must be educated on the **REMS requirements and on dispensing procedures for the treatment**
- Pharmacy must ensure that every prescription includes:
  - Patient and prescriber demographics and contact information
  - Dosing information and instructions
  - Prescriber signature
  - Patient Risk Category
  - Valid Authorization Number
- Authorization numbers are valid for **7 days** from the date of last pregnancy test for female patients who can get pregnant and **30 days** from the date it is issued for all other patients
- No automatic refills or telephone prescriptions are permitted
- Faxed prescriptions are permissible depending on state laws

## Dispensing guidelines

- Dispense **no more than a 4-week (28-day) supply** with the **Medication Guide**. A new prescription is required for further dispensing
- **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription**
- Dispense or ship the product within 24 hours of obtaining and recording the confirmation number
- For females who can get pregnant, product **must be shipped the same day** confirmation number is obtained **or picked-up within 24 hours** of obtaining confirmation number
- Pharmacy is required to **cancel** the confirmation number if product is not provided to the patient within the required time frame
- Pharmacy must obtain a new confirmation number by accessing the Pomalidomide REMS Pharmacy Portal or by calling the Pomalidomide REMS Coordinating Center at 1-866-245-7925 when ready to ship or have the product picked up

## Dispensing guidelines (continued)

- When shipping, pharmacy must require a signature confirming receipt
- Pharmacy shall keep an inventory log for the drug, by strength, reflecting its on-hand inventory at all times
- Do not distribute, transfer, loan, or sell pomalidomide, except with the permission of the Pomalidomide REMS
- Accept unused capsules (previously dispensed) from a patient or patient caregiver for proper disposal

# Steps for dispensing

## Review incoming prescriptions

- Only accept prescriptions with all of the following information:
  - Patient and prescriber demographics and contact information
  - Dosing information and instructions
  - Prescriber signature
  - Patient Risk Category
  - Valid Authorization Number
- Make sure the prescription is signed and dated
- Confirm the prescription is written for a 4-week (28-day) supply or less
- For subsequent prescriptions, verify there are 7 days or less of therapy remaining on the existing prescription

## Steps for dispensing (continued)

### Counsel patient

- Patients must receive counseling from a Pomalidomide REMS certified pharmacy counselor
- Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist
  - Make sure form is signed and dated by the counselor and appropriate boxes are checked off
  - Keep a copy of the checklist and the associated prescription
- Please report adverse drug experiences that are suspected to be associated with the use of the drug and any suspected pregnancy occurring during the treatment

## Steps for dispensing (continued)

- **Obtain confirmation number from the Pomalidomide REMS Pharmacy Portal**
- Prior to each prescription, access the Pomalidomide REMS Pharmacy Portal or contact the Pomalidomide REMS Coordinating Center at 1-866-245-7925, available 8:00AM- 8:00PM, Monday- Friday.
  1. Search Certified Prescriber (name and National Provider Identifier (NPI))
  2. Search Enrolled Patient (name and date of birth)
  3. Enter Authorization Number
  4. Enter Number of Capsules and Milligram Strength
  5. Generate Confirmation Number
  6. Document Confirmation Number
- If you do not obtain a confirmation number, you are not permitted to dispense the product to the patient
- If you have questions about the validity of the prescribers authorization or pharmacy confirmation numbers, call the Pomalidomide REMS Coordinating Center.

## Steps for dispensing (continued)

- **Dispense prescription**
  - Include a **Medication Guide** with each prescription
  - Document the dispense date on either the shipping receipt or pharmacy dispensing log
  - Dispense or ship the product within 24 hours of obtaining and recording the confirmation number
  - For females who can get pregnant, product **must be shipped the same day** confirmation number is obtained **or handed to the patient within 24 hours**

## Pharmacy staff knowledge check

- An confirmation number is valid for:
  - A. 24 hours
  - B. 7 days
  - C. 30 days

## Pharmacy staff knowledge check

- An confirmation number is valid for:
  - A. 24 hours
  - B. 7 days
  - C. 30 days

**Correct Answer: A. 24 hours**

- The confirmation number is **only valid for 24 hours**
- Pharmacy is required to **cancel** the confirmation number if product is not provided to the patient within the required time frame

## Pomalidomide REMS (continued)

- For more information on the Pomalidomide REMS:
  - Call the Pomalidomide REMS Coordinating Center at 1-866-245-7925
  - Visit the Pomalidomide REMS Website at [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com)

### **Did you know?**

The Pomalidomide REMS Coordinating Center has Specialists to educate and train pharmacy staff on the Pomalidomide REMS program guidelines and compliance.

# Pomalidomide Risk Evaluation and Mitigation Strategy (REMS) Pharmacy Certification Quiz

**Instructions:** The Pomalidomide REMS [Pharmacy Certification Quiz](#) will be completed through the Pomalidomide REMS Website via the Pharmacy Portal. This quiz will be completed only once at the time of pharmacy enrollment and a passing score of 100% is needed for your pharmacy to become certified in the Pomalidomide REMS.

**Pharmacy Name:** \_\_\_\_\_

**Authorized Representative Name:** \_\_\_\_\_

1. Authorization numbers for females who can get pregnant are valid for up to \_\_\_\_\_.  
 a. 7 days  
 b. 10 days  
 c. 14 days  
 d. 28 days
2. It is not necessary to obtain a confirmation number to dispense.  
 a. True  b. False
3. The Pomalidomide REMS is mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for pomalidomide treatment.  
 a. True  b. False
4. It is not required to retain the prescription with the authorization and confirmation numbers for each filled prescription.  
 a. True  b. False
5. It is not necessary to complete the [Education and Counseling Checklist for Pharmacies](#).  
 a. True  b. False
6. According to pomalidomide's Prescribing Information, boxed warnings and warnings and precautions, deep venous thrombosis, pulmonary embolism, myocardial infarction and stroke have been reported in patients receiving pomalidomide.  
 a. True  b. False
7. Pomalidomide can cause serious birth defects.  
 a. True  b. False
8. What pregnancy precautions are required for a female who can get pregnant with respect to heterosexual sexual contact?  
 a. Must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time she has sex with a male, beginning at least 4 weeks before therapy, during therapy (including dose interruptions), and for at least 4 weeks after stopping therapy  
 b. Abstain from having any heterosexual sexual contact only while taking therapy  
 c. After stopping therapy it is okay to get pregnant at any time  
 d. Use 2 forms of birth control 2 weeks before taking therapy
9. What precautions are required for a male with respect to sexual contact with his female partner who can get pregnant?  
 a. Use of a latex or synthetic condom every time he has sexual intercourse with a female who can get pregnant during therapy (including dose interruptions) and for 4 weeks after stopping therapy, even if he has undergone a successful vasectomy  
 b. Abstain from having any sexual contact with females who can get pregnant only while taking therapy  
 c. Use latex or synthetic condoms while taking therapy. No precautions are necessary once treatment has stopped  
 d. Males taking therapy who have had a vasectomy do not need to use latex or synthetic condoms
10. For the Pomalidomide REMS, female patients who can get pregnant must have a negative pregnancy test:  
 a. Prior to initial prescription  
 b. Prior to subsequent prescription  
 c. Prior to initial prescription and prior to subsequent prescription  
 d. None of these
11. Adverse drug experiences that are suspected to be associated with the use of therapy, and any suspected pregnancy occurring during treatment, must be reported to the Pomalidomide REMS.  
 a. True  b. False
12. The Medication Guide must be provided every time pomalidomide is dispensed.  
 a. True  b. False
13. A certified Pomalidomide REMS pharmacy cannot dispense more than a \_\_\_\_\_ supply of pomalidomide.  
 a. 28 day  
 b. 3 month  
 c. 2 week  
 d. 1 year
14. Authorization numbers for patient risk categories other than females who can get pregnant are valid for up to \_\_\_\_\_.  
 a. 30 days  
 b. 10 days  
 c. 7 days  
 d. 28 days
15. A male patient can donate sperm at any time during therapy.  
 a. True  b. False

## Pharmacy Certification Quiz Answer Key

1. Authorization numbers for females who can get pregnant are valid for up to \_\_\_\_\_.  
 a. 7 days
2. It is not necessary to obtain a confirmation number to dispense.  
 b. False
3. The Pomalidomide REMS is mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for pomalidomide treatment.  
 a. True
4. It is not required to retain the prescription with the authorization and confirmation numbers for each filled prescription.  
 b. False
5. It is not necessary to complete the *Education and Counseling Checklist for Pharmacies*.  
 b. False
6. According to pomalidomide's Prescribing Information, boxed warnings and warnings and precautions, deep venous thrombosis, pulmonary embolism, myocardial infarction and stroke have been reported in patients receiving pomalidomide.  
 a. True
7. Pomalidomide can cause serious birth defects.  
 a. True
8. What pregnancy precautions are required for a female who can get pregnant with respect to heterosexual sexual contact?  
 a. **Must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time she has sex with a male, beginning at least 4 weeks before therapy, during therapy (including dose interruptions), and for at least 4 weeks after stopping therapy**
9. What precautions are required for a male with respect to sexual contact with his female partner who can get pregnant?  
 a. **Use of a latex or synthetic condom every time he has sexual intercourse with a female who can get pregnant during therapy (including dose interruptions) and for 4 weeks after stopping therapy, even if he has undergone a successful vasectomy**
10. For the Pomalidomide REMS, female patients who can get pregnant must have a negative pregnancy test:  
 c. **Prior to initial prescription and prior to subsequent prescription**
11. Adverse drug experiences that are suspected to be associated with the use of therapy, and any suspected pregnancy occurring during treatment, must be reported to the Pomalidomide REMS.  
 a. True
12. The Medication Guide must be provided every time pomalidomide is dispensed.  
 a. True
13. A certified Pomalidomide REMS pharmacy cannot dispense more than a \_\_\_\_\_ supply of pomalidomide.  
 a. 28 days
14. Authorization numbers for patient risk categories other than females who can get pregnant are valid for up to \_\_\_\_\_.  
 a. 30 days
15. A male patient can donate sperm at any time during therapy.  
 b. False



# **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
- 

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## Risks of Pomalidomide

Pomalidomide is similar to the medicine thalidomide (THALOMID®)<sup>1</sup>. 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](http://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](http://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](http://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](http://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](http://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](http://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](http://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](http://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](http://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](http://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](http://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**



Planned Parenthood is the nation's leading provider and advocate of high-quality, affordable health care for women, men, and young people, as well as the nation's largest provider of sex education. With approximately 700 health centers across the country, Planned Parenthood organizations serve all patients with care and compassion, with respect and without judgment. Through health centers, programs in schools and communities, and online resources, Planned Parenthood is a trusted source of reliable health information that allows people to make informed health decisions. We do all this because we care passionately about helping people lead healthier lives.

[www.plannedparenthood.org](http://www.plannedparenthood.org)  
[www.ppfastore.org](http://www.ppfastore.org)

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**What You Should Know About Emergency Contraception**  
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ISBN 1-934100-43-2  
Printed in the U.S.A.



Birth  
Control  
Series

## What You Should Know About Emergency Contraception



# TOP 3 THINGS



## What you should know about emergency contraception (EC)

- 1 EC can prevent pregnancy after you have had unprotected vaginal sex.
- 2 EC must be used within 120 hours (5 days) after vaginal sex.
- 3 There are two different kinds of EC:
  - Copper IUD (ParaGard®)
  - Emergency contraception pills

### You can use EC if:

- You weren't using any birth control when you had sex.
- You made a mistake with your regular birth control.
- The condom broke or slipped off.
- Your partner didn't pull out in time.
- You were forced to have unprotected vaginal sex.

## Copper (ParaGard) IUD as Emergency Contraception

The ParaGard IUD can be used for emergency contraception if put in within 5 days after sex. It is the most effective kind of EC. The IUD is a birth control method that is put into your uterus (womb) by a doctor or nurse and it can stay there as birth control for up to 12 years if you want. It works really well (99% effective) and you don't have to do anything once it's in.



### How the IUD Works

Pregnancy doesn't happen right after sex. It can take up to 6 days for the sperm and egg to meet after having sex. The IUD works mostly by changing the way sperm move so they can't join with an egg. If sperm cannot join with an egg, pregnancy cannot happen.

## Emergency Contraception Pills

Emergency contraception pills are also called the “morning-after pill.” There are two different kinds of emergency contraception pills:

- ella<sup>®</sup> is very effective at preventing pregnancy if taken within 5 days after sex. It is the most effective EC pill, and it stays just as effective for all 5 days. If you are breastfeeding, you will have to pump and throw away the breast milk for 36 hours after taking it.
- Levonorgestrel EC pills, sold as Plan B One-Step<sup>®</sup>, Next Choice One Dose<sup>®</sup> and others, are also pretty effective. You can take these up to 5 days after having sex but they work better the sooner you take them. They may also be less effective for overweight women.



## How EC Pills Work



Emergency contraception pills work by keeping a woman's ovary from releasing an egg for longer than usual. Pregnancy cannot happen if there is no egg to join with sperm. EC will not hurt an existing pregnancy or cause an abortion.

## If You Are Overweight or Obese

Levonorgestrel EC pills may not work as well for overweight or obese women. If you are overweight or obese, the best kind of EC for you is the IUD. If you can't get an IUD, use ella.

## How to Get EC Pills

Anyone, regardless of age or gender, can get EC pills (except ella) over-the-counter, without a prescription, at their local drugstore. You will usually find it in the family planning aisle or near the pharmacy. If you don't see it there, ask the pharmacist. You need a prescription for ella. You can ask your doctor or nurse, or go to [www.ella-kwikmed.com](http://www.ella-kwikmed.com) to get a prescription and buy ella online.

The cost of emergency contraception pills depends on your insurance, where you live, and whether you get it from the drugstore or a health center. You may be able to get it cheaper at a Planned Parenthood health center. It may cost anywhere from \$10 to \$70.

### Get EC Before You Need It

You may want to buy EC or ask your doctor or nurse for a prescription for ella before you need it. This way, you will have it when you need it and can take it quickly.

## Possible Side Effects

- Your next period may come earlier or later than usual.
- You may have more or less bleeding than usual during your next period.
- Your breasts may feel sore, and you might be dizzy or have headaches.
- You may feel nauseous after taking EC. If you vomit within three hours of taking EC, you need to take it again.
- Using EC a lot may make your periods happen at different times each month.

There have been no serious complications among the millions of women who have used EC pills. Side effects usually stop after a day or two.

## After You Take EC

- EC does not always work. If you do not get your period within three weeks of taking EC, or if you have symptoms of pregnancy such as having to pee a lot, being very tired, or feeling nauseous, you should take a pregnancy test.
- It is safe to use EC as often as you need it. But, if you find yourself using it a lot, you may want to consider using a better birth control method like the IUD, shot, or pill.

## EC and Sexually Transmitted Infections

Emergency contraception does not protect you from getting a sexually transmitted infection. You should talk to a doctor or nurse about getting tested.

## Choosing What Type of EC to Use

Here are some things to think about if you need EC:



- The Copper IUD is the most effective type of EC. It can be used as your regular birth control for up to 12 years. The most effective EC pill is ella.
- Levonorgestrel EC pills are the easiest to get quickly because you can buy them over-the-counter, without a prescription, in a drugstore.
- Levonorgestrel EC pills may not work as well for women who are overweight. The IUD or ella is a better option.

## Want More Info?



Our website:  
[PlannedParenthood.org](http://PlannedParenthood.org)



Facebook:  
[Planned Parenthood](https://www.facebook.com/PlannedParenthood)



Twitter:  
[@PPFA](https://twitter.com/PPFA)



Tumblr:  
[plannedparenthood.tumblr.com](http://plannedparenthood.tumblr.com)



Instagram:  
[@PlannedParenthood](https://www.instagram.com/PlannedParenthood)

# **PATIENT RESOURCE PACK**

## **Pomalidomide Risk Evaluation and Mitigation Strategy (REMS) Program**

### **The Patient Resource Pack contains:**

- **Patient Guide**
- **Emergency Contraception Brochure**
- **Medication Guide<sup>1</sup>**

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

Please see Prescribing Information<sup>2</sup>, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.

<sup>1</sup> Please note, the enclosed materials include Medication Guide from each generic pomalidomide manufacturer participating in the Pomalidomide REMS.

<sup>2</sup> Please note, the enclosed materials include Prescribing Information from each generic pomalidomide manufacturer participating in the Pomalidomide REMS.

## Education and Counseling Checklist for Pharmacies

PHARMACY INFORMATION			
Pharmacy Name:			
Street Address:	City:	State:	ZIP Code:
Counselor Name:	Work Phone Number:		
PATIENT INFORMATION			
Patient Name:	Date of Birth:		
REMS CONFIRMATION			
Prescription Authorization Number:		Authorization Date:	
Patient Risk Category: <input type="checkbox"/> Adult Female Who Can Get Pregnant <input type="checkbox"/> Female Child Who Can Get Pregnant <input type="checkbox"/> Adult Female Who Cannot Get Pregnant <input type="checkbox"/> Female Child Who Cannot Get Pregnant <input type="checkbox"/> Adult Male <input type="checkbox"/> Male Child			
Confirmation Prescriber is Certified, Patient is Enrolled and Not Pregnant (if applicable) and the Authorization Number Provided by the Prescriber is Valid: <input type="checkbox"/> Yes <input type="checkbox"/> No		Confirmation Number: Confirmation Date:	
Checklist for Adult Female or Female Child Who Can Get Pregnant			
<input type="checkbox"/> I will make sure that patients are aware that they will receive the Medication Guide along with their prescription			
<b>I COUNSELED ADULT FEMALE OR FEMALE CHILD WHO CAN GET PREGNANT ON:</b>			
<input type="checkbox"/> Potential embryo-fetal toxicity			
<input type="checkbox"/> Not taking pomalidomide if pregnant or breastfeeding			
<input type="checkbox"/> Using <b>at the same time</b> 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— <b>every time</b> they have sex with a male, or abstaining from sex with a male			
<input type="checkbox"/> Continuing to use at the <b>same time</b> 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 <b>every time they have sex with a male</b> , or abstaining from sex with a male			
<input type="checkbox"/> 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).			
<input type="checkbox"/> Obtaining a pregnancy test—performed by their healthcare provider—at the required testing schedule:			
<ul style="list-style-type: none"> <li>• Before treatment initiation (first prescription):                             <ul style="list-style-type: none"> <li>• 10-14 days prior to initiation of pomalidomide therapy</li> <li>• Within 24 hours of the initial prescription</li> </ul> </li> <li>• During treatment:                             <ul style="list-style-type: none"> <li>• Weekly during the first 4 weeks of use</li> <li>• Thereafter,                                     <ul style="list-style-type: none"> <li>• Every 4 weeks for female patients who can get pregnant with regular menstrual cycles</li> <li>• Every 2 weeks for female patients who can get pregnant with irregular menstrual cycles</li> </ul> </li> </ul> </li> </ul>			
<input type="checkbox"/> 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			
<input type="checkbox"/> Possible side effects include deep vein thrombosis, pulmonary embolism, myocardial infarction and stroke			
<input type="checkbox"/> Not sharing pomalidomide capsules with anyone			
<input type="checkbox"/> Keeping pomalidomide out of reach of children			
<input type="checkbox"/> Not donating blood while taking pomalidomide (including dose interruptions) and for 4 weeks after stopping pomalidomide			
<input type="checkbox"/> Not breaking, chewing, or opening pomalidomide capsules			
<input type="checkbox"/> Instructions on pomalidomide dose and administration Milligram (mg) Strength: _____ Number of Capsules Dispensed: _____			
<b>FEMALE CHILDREN (&lt;18 YEARS OF AGE) WHO CAN GET PREGNANT:</b>			
<input type="checkbox"/> Parent or legal guardian must have read the Pomalidomide REMS educational material and agreed to ensure compliance			

## Checklist for Adult Female or Female Child Who Cannot Get Pregnant

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

### **I COUNSELED ADULT FEMALE OR FEMALE CHILD WHO CANNOT GET PREGNANT ON:**

- Possible side effects include deep vein thrombosis, pulmonary embolism, myocardial infarction and stroke  
 Not sharing pomalidomide capsules with anyone  
 Keeping pomalidomide out of reach of children  
 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) WHO CANNOT GET PREGNANT:**

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

## Checklist for Adult Male or Male Child

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

### **I COUNSELED ADULT MALE OR MALE CHILD 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 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  
 Keeping pomalidomide out of reach of children  
 Not donating 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 CHILD (<18 YEARS OF AGE):**

- Parent or legal guardian must have read the 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 the Pomalidomide REMS, please visit [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com), or call the REMS Coordinating Center at 1-866-245-7925.

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

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

## POMALIDOMIDE REMS

# Pomalidomide REMS

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## Welcome to the Pomalidomide REMS

The Pomalidomide REMS (Risk Evaluation and Mitigation Strategy) is a safety program that manages the serious risks of pomalidomide. The Pomalidomide REMS is required by the Food and Drug Administration (FDA).

### Important information about pomalidomide and the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS)

- Only prescribers and pharmacies certified by the Pomalidomide REMS can prescribe and dispense pomalidomide to patients.
- Patients must be enrolled in the Pomalidomide REMS and follow all the safety rules in the REMS order to receive pomalidomide.

#### 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)

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**Report adverse drug experiences that are suspected to be associated with the use of pomalidomide and any suspected pregnancy occurring during treatment with pomalidomide to the Pomalidomide REMS Coordinating Center by calling 1-866-245-7925, or to the FDA by visiting [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

For additional Pomalidomide REMS Information, please contact the Pomalidomide REMS at:

PHONE: 1-866-245-7925  
FAX: 1-844-872-5446

[Month Year of Approval] XXXXXXXXXXXXX

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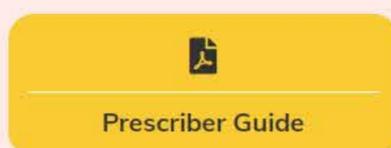
## Prescribers

### Key points of the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS)

- The prescriber enrolls and becomes certified in the Pomalidomide REMS
- The prescriber counsels patient on benefits and risks of pomalidomide
- The prescriber provides contraception and emergency contraception counseling
- The prescriber verifies negative pregnancy test for all female patients who can get pregnant
- The prescriber completes a *Patient-Physician Agreement Form* with each patient and sends to the REMS Coordinating Center
- The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from the Pomalidomide REMS and receives confirmation that all REMS requirements have been met and is authorized to write the prescription and send to a Pomalidomide REMS certified pharmacy
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber must document the authorization number and patient risk category on each prescription
- The prescriber sends the pomalidomide prescription to a certified pharmacy

### Learning more about the Pomalidomide REMS

For additional information about the Pomalidomide REMS, please see the educational materials below.



### Enrolling in the Pomalidomide REMS

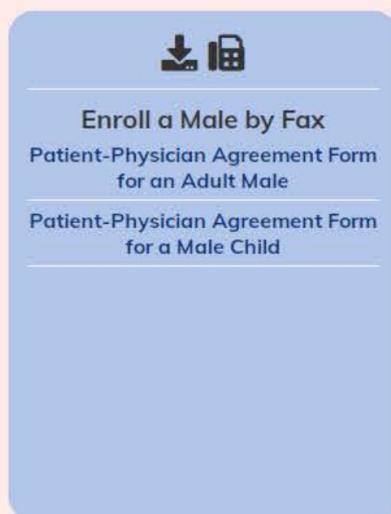
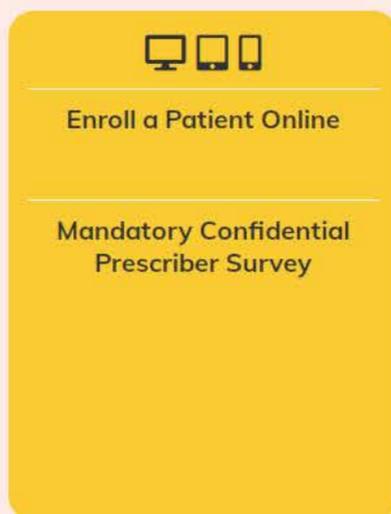
In order to prescribe pomalidomide, you must enroll in the Pomalidomide REMS and agree to follow the requirements of the program.

You can complete the *Prescriber Enrollment Form* online or download the *Prescriber Enrollment Form* below and fax it to the Pomalidomide REMS at 1-844-872-5446.



### Prescribing pomalidomide for your patients

In order to receive pomalidomide, your patients must also be enrolled in the Pomalidomide REMS. You can enroll your patients using the appropriate *Patient-Physician Agreement Form* available online or download the *Patient-Physician Agreement Form* below and fax it to the Pomalidomide REMS at 1-844-872-5446. You and your patients can also complete your mandatory confidential surveys online or by telephone interview.



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Report adverse drug experiences that are suspected to be associated with the use of pomalidomide and any suspected pregnancy occurring during treatment with pomalidomide to the Pomalidomide REMS Coordinating Center by calling 1-866-245-7925, or to the FDA by visiting [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

For additional Pomalidomide REMS Information, please contact the Pomalidomide REMS at:

PHONE: 1-866-245-7925  
FAX: 1-844-872-5446

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# Pomalidomide REMS

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## Patients

### What you need to know about the Pomalidomide REMS

Your doctor will enroll you in the Pomalidomide REMS so that you can receive your medication. Use the materials below to learn more about the Pomalidomide REMS, and what you need to do.

[Patient Guide](#)[Medication Guide](#)[Mandatory Confidential Patient Survey Online](#)[Emergency Contraception Brochure](#)

### Attention Females Who Can Get Pregnant

Unless you abstain from sexual intercourse with a male partner, you are required to use **at the same time** at least 1 highly effective birth control method and at least 1 additional effective method **every time** you have sex with a male. Below, you will find a printable letter that you can bring with you to your next medical appointment that discusses your reproductive health. This will help you and your healthcare provider understand what types of birth control options are best for you.

[Birth Control Options to Discuss With Your Healthcare Provider](#)

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PHONE: 1-866-245-7925  
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## Patients

### Mandatory Confidential Patient Survey

To begin, please enter your identifying information and click "Continue".

#### Patient Identifying Information

Your REMS ID was provided when you enrolled. If you do not have your REMS ID, or did not receive it, please contact the Pomalidomide REMS Coordinating Center by calling 1-866-245-7925.

Fields marked with an \* are required.

\*REMS ID

First Name

Last Name

CONTINUE

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For additional Pomalidomide REMS Information, please contact the Pomalidomide REMS at:

PHONE: 1-866-245-7925  
FAX: 1-844-872-5446

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## Patients

### Mandatory Confidential Patient Survey

You are not required to submit a patient survey at this time. Your last submission was 99/99/9999. Your next survey can be completed beginning 99/99/9999.

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## Patients

### Mandatory Confidential Patient Survey

The survey you previously submitted did not meet the REMS requirements. Please contact your prescriber in order to retake the survey.

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## Patients

### Mandatory Confidential Patient Survey

Please read each question carefully and select your response.

#### Patient Identifying Information

REMS ID: 123456

First Name: Peggy

Last Name: Sue

#### Patient Initial Survey: Adult Female Who Can Get Pregnant

Fields marked with an \* are required.

\* Pomalidomide can cause severe birth defects or death to unborn babies of females taking pomalidomide.

True  False

\* Have you had both of your ovaries or your uterus surgically removed?

Yes  No

\* Have you been in natural menopause for at least 2 years?

Yes  No

\* What was the date of your last pregnancy test?

\* What was the result of your last pregnancy test?

Positive  Negative  Cannot be determined  Unknown

\* Have you had sex with a male partner in the past 4 weeks?

Yes  No

\* If you are sexually active, are you aware of using 2 methods of birth control, as required for at least the past 4 weeks?

Yes  No

\* Have there been any instance of having sexual intercourse without using 2 forms of birth control?

Yes  No

\* Do you have any reason to think that you may be pregnant?

Yes  No  I am not sure

\* Are you currently breastfeeding?

Yes  No

\* Will you return any unused pomalidomide to the pharmacy that dispensed the pomalidomide or to your prescriber for proper disposal?

Yes  No

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## Patients

### Mandatory Confidential Patient Survey

Thank you for submitting the confidential Patient Survey. Your prescriber will be notified of the survey completion.

For more information please contact your prescriber or the Pomalidomide REMS by calling 1-866-245-7925.

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## Patients

### Mandatory Confidential Patient Survey

Thank you for submitting the confidential Patient Survey.

At least one of your answers did not meet the REMS requirements. Your prescriber may be contacting you to review your answers and will let you know when you should re-take the survey.

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## Pharmacies

### Key points of the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS)

- The pharmacy certifies in the Pomalidomide REMS
- The certified pharmacy counsels the patient, and completes the *Education and Counseling Checklist for Pharmacies*
- The certified pharmacy must obtain a confirmation number from the Pomalidomide REMS Portal before dispensing
- The certified pharmacy dispenses pomalidomide to the patient along with a Medication Guide

### Pomalidomide REMS information for certified pharmacies

Pomalidomide is only dispensed from Pomalidomide REMS certified pharmacies.

As a Pomalidomide REMS certified pharmacy, you must follow the requirements of the Pomalidomide REMS. You may enroll your pharmacy using the pharmacy enrollment form below. You can complete pharmacy enrollment online or download the *Pharmacy Enrollment Form* below and fax it to the Pomalidomide REMS at 1-844-872-5446.

[Enroll a Pharmacy Online](#)[Enroll a Pharmacy by Fax](#)

For more information on the Pomalidomide REMS, you can download the *Pharmacy Guide*, *Pharmacy Training* and the *Education and Counseling Checklist for Pharmacies*. Please also see the full prescribing information below.

[Pharmacy Guide](#)[Education and Counseling Checklist for Pharmacies](#)[Pharmacy Training](#)[Prescribing Information](#)

### The Pomalidomide REMS Pharmacy Portal

Eligible pharmacies can obtain authorization numbers using the Pomalidomide REMS Pharmacy Portal.

[Log in to the Pomalidomide REMS Pharmacy Portal](#)

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## Login

### Login

Your username was supplied to you via email when you registered. If you need assistance, please call 1-866-245-7925.

Please enter your username

LOGIN

[Forgot Username](#)

OR

## Do not have an online account?



### Registration

To create your web account for the Pomalidomide REMS, please complete the fields below.

Fields marked with an \* are required.

\*NPI

\*I am a

Prescriber  Pharmacy

CONTINUE

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## Certified Pharmacy Lookup

Below is a list of all pharmacies dispensing pomalidomide

-  Download the list to spreadsheet format by clicking on the Excel icon just above the column headers
-  Search/Filter the list by entering information in the text box below any column header
-  Sort the list by clicking on any column header

			
Name 	Phone Number 	Fax Number 	Pharmacy Type 
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Testing Pharmacy	546-546-4545	564-564-5646	Inpatient

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## List of products covered under the Pomalidomide REMS

Drug Name	Dosage	Company	Contact	Links
				<a href="#">Important Safety Information</a> <a href="#">Prescribing Information</a> <a href="#">Patient Medication Guide</a>
				<a href="#">Important Safety Information</a> <a href="#">Prescribing Information</a> <a href="#">Patient Medication Guide</a>

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## Account Submitted Successfully

A confirmation of this submission has been sent to the email address provided. You can expect to receive 2 emails, one contains your username and the second contains your temporary password. Please login with the username provided. You will then be prompted to update your password.

If you do not receive the emails within the next few hours, or would like to update your enrollment information at any time, please contact the Pomalidomide REMS at 1-866-245-7925.

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