

# 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:

---

#### 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>

---

	<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>

---

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.

---

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.

---

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

---

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](#).

---

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

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

---

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.
-

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>
-----------------------------	---

	<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>

---

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

---

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>
-----------------------------	--

---

	6. Receive counseling from the pharmacy to inform their pomalidomide prescriber when the patient begins menses.
During treatment; before each prescription	7. Receive counseling from the prescriber on the need to complete the patient survey. 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. 9. Receive counseling from the pharmacy to inform their pomalidomide prescriber when the patient begins menses. 10. Complete the patient survey.
During treatment and after treatment discontinuation; for 4 weeks	11. Adhere to the safe-use conditions: not donating blood.
At all times	12. Inform the prescriber when the patient begins menses. 13. Return unused pomalidomide to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide. 14. Adhere to safe-use conditions: Not sharing pomalidomide; not breaking, chewing, or opening pomalidomide capsules; and keeping pomalidomide out of reach of children.

---

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

---

Before treatment initiation	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. 2. Review the <a href="#">Patient Guide</a> and the <a href="#">Emergency Contraception Brochure</a> . 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. 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. 5. Receive counseling from the pharmacy on embryo-fetal toxicity with exposure to pomalidomide, barrier contraception requirements, and not donating sperm.
-----------------------------	--

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>
---------------------------------	---

- 
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.
- 

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.
-

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](#)