

Risk Evaluation and Mitigation Strategy (REMS) Document

A. NDA 204410 Opsumit¹ (macitentan) REMS Program

I. Administrative Information

Application Number: NDA 204410

Application Holder: Actelion Pharmaceuticals Ltd Initial

REMS Approval: 10/2013

Most Recent REMS Update: 04/2020

II. REMS Goal

The goal of the Opsumit REMS Program is to mitigate the risk of embryo-fetal toxicity associated with Opsumit by:

1. Ensuring prescribers are educated on the following:
 - the risks of embryo-fetal toxicity
2. Ensuring prescribers are educated on and adhere to the following:
 - counseling patients about these risks and the need for monthly monitoring
 - enrolling patients in the Opsumit REMS Program
 - monitoring patients at baseline and monthly
3. Ensuring that pharmacies are educated on the following:
 - the risks of embryo-fetal toxicity
4. Ensuring that pharmacies are educated on and adhere to the following:
 - confirming that the appropriate patient monitoring and counseling has occurred before dispensing Opsumit
5. Ensuring that patients are informed about:
 - the risks of embryo-fetal toxicity
 - appropriate baseline and monthly patient monitoring
 - appropriate contraception

III. REMS Requirements

Actelion Pharmaceuticals Ltd must ensure that healthcare providers, patients, pharmacies, and wholesalers-distributors comply with the following requirements:

1. Healthcare providers who prescribe Opsumit must:

To become certified to prescribe

1. Review the drug's Prescribing Information
2. Review the following: [Prescriber and Pharmacy Guide](#).
3. Enroll in the REMS by completing the [Prescriber Enrollment Form](#) and submitting it to the REMS Program
4. For all females: Assess the patient's reproductive status using the

¹ Opsumit-specific requirements contained in this document apply until the date of full approval of the first abbreviated new drug application (ANDA) joining a shared system REMS with Opsumit.

definitions in the [Prescriber and Pharmacy Guide](#). Document and submit the results to the REMS Program using the [Patient Enrollment Form](#).

5. For all females: Counsel the patient that the drug is only available through a restricted distribution program.
6. For females of reproductive potential: Assess the patient's pregnancy status by ordering and reviewing her pregnancy test result
7. For females of reproductive potential: Counsel the patient on the risk of embryo-fetal toxicity, the need to use reliable contraception, and emergency contraception using the [Guide for Female Patients](#).
8. For pre-pubertal females: Counsel the patient on the risk of embryo- fetal toxicity and to immediately contact her prescriber if she begins to menstruate - using the [Guide for Female Patients](#).
9. Enroll all female patients by completing and submitting the [Patient Enrollment Form](#) and submitting it to the REMS Program.

During treatment;
before each
prescription

10. For females of reproductive potential: Counsel the patient if she is not complying with required testing, if she is not using appropriate contraception, and to contact her prescriber if she misses a menstrual period or suspects that she is pregnant.
11. For females of reproductive potential: Assess the patient's pregnancy status by ordering and reviewing her pregnancy test result.

During treatment;
at least annually

12. For pre-pubertal females at least age 8 years or older: Document reproductive potential status and submit to the REMS Program using the [Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#).

After treatment
discontinuation;
one month

13. For females of reproductive potential: Assess the patient's pregnancy status by ordering and reviewing her pregnancy test result.

At all times

14. For pre-pubertal females: Assess the patient's reproductive status.
15. Report pregnancies to Actelion Pharmaceuticals Ltd.

At all times; within
10 business days

16. Report a change or misclassification in reproductive status to the REMS Program using the [Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#).

2. Females of reproductive potential who are prescribed Opsumit:

Before treatment
initiation

1. Review the [Guide for Female Patients](#).
2. Get a pregnancy test.
3. Enroll in the REMS by completing the [Patient Enrollment Form](#) with the

prescriber. Enrollment information will be provided to the REMS Program.

4. Receive counseling from the prescriber on the risk of embryo-fetal toxicity, the need to use reliable contraception, and emergency contraception using the [Guide for Female Patients](#).
5. Adhere to the safe use condition: Communicate with the pharmacy to confirm completion of pregnancy testing.

During treatment;
before each
dispensing

6. Receive counseling from the pharmacy or healthcare provider who dispenses Opsumit on the risk of embryo-fetal toxicity, the need for reliable contraception during treatment and for one month after stopping treatment, to get monthly pregnancy tests, and to report a pregnancy immediately.
7. Get a pregnancy test.
8. Adhere to the safe use condition: Communicate with the pharmacy to confirm completion of pregnancy testing.

During treatment
and after
treatment
discontinuation for
one month

9. Adhere to the safe use condition: Use reliable contraception as described in the [Guide for Female Patients](#).
10. Agree to be contacted by the manufacturer if you become pregnant.

After treatment
discontinuation;
one month

11. Get a pregnancy test.

At all times

12. Inform the prescriber immediately if you miss a menstrual period or suspect a pregnancy.

3. Pre-pubertal females who are prescribed Opsumit:

Before treatment
initiation

1. Review the [Guide for Female Patients](#).
 2. Enroll in the REMS Program by completing the [Patient Enrollment Form](#) with the prescriber. Enrollment information will be provided to the REMS Program.
 3. Receive counseling from the prescriber on the risk of embryo-fetal toxicity and to contact your prescriber if you begin to menstruate using the [Guide for Female Patients](#).
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| At all times | <ol style="list-style-type: none">4. If over the age of 8: Be monitored for a change in reproductive status.5. Inform the prescriber if there is a change in reproductive status. |
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4. Post-menopausal females or females with other medical reason for permanent, irreversible infertility who are prescribed Opsumit:

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| Before treatment initiation | <ol style="list-style-type: none">1. Review the Guide for Female Patients.2. Enroll in the REMS Program by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS Program. |
| At all times | <ol style="list-style-type: none">3. Inform the prescriber if there is a change in your reproductive status. |
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5. Outpatient pharmacies that dispense Opsumit must:

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| To become certified to dispense | <ol style="list-style-type: none">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.2. Train all relevant staff involved in dispensing on the Opsumit REMS Program requirements, procedures and REMS materials.3. Establish processes and procedures to verify the female patient is enrolled, the reproductive status of the patient has not changed, and the prescriber is certified.4. For females of reproductive potential: Establish processes and procedures to verify that pregnancy testing is complete or the prescriber authorizes the refill. |
| Before dispensing | <ol style="list-style-type: none">5. For females of reproductive potential: Counsel the patient on the risk of embryo-fetal toxicity, the need to use reliable contraception during treatment and for one month after stopping treatment, to get monthly pregnancy tests, and inform the prescriber of a pregnancy immediately.6. Verify the female patient is enrolled, the reproductive status has not changed, and the prescriber is certified through the processes and procedures established as a requirement of the REMS Program.7. For females of reproductive potential: Verify that pregnancy testing is complete or the prescriber authorizes the refill through the processes and |
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procedures established as a requirement of the REMS Program.

8. For females of reproductive potential: Dispense no more than a 30-days' supply.

At all times

9. Report pregnancies to Actelion Pharmaceuticals, Ltd.
10. Not distribute, transfer, loan, or sell Opsumit except to certified dispensers.
11. For females of reproductive potential: Maintain and submit records of daily product dispensing data.
12. Maintain records that all processes and procedures are in place and are being followed.
13. Comply with audits carried out by the manufacturer or a third party acting on behalf of the manufacturer to ensure that all processes and procedures are in place and are being followed.

6. Inpatient pharmacies that dispense Opsumit must:

To become certified to dispense

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.
 2. Have the authorized representative enroll in the REMS Program by completing the [Inpatient Pharmacy Enrollment Form](#) and submitting it to the REMS Program.
 3. Have the authorized representative review the Prescribing Information and the [Prescriber and Pharmacy Guide](#).
 4. Train all relevant staff involved in dispensing Opsumit on the REMS Program requirements, procedures and REMS materials.
 5. Establish processes and procedures to verify the female patient is enrolled in the REMS program or will be enrolled prior to discharge, her reproductive status, and the female patient is under the supervision and care of a certified prescriber.
 6. For females of reproductive potential: establish processes and procedures to verify pregnancy testing is complete, and that the patient is counseled on the risk of embryo-fetal toxicity, the need to use reliable contraception, to get monthly pregnancy tests, and to inform the prescriber of a
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pregnancy immediately.

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| Before dispensing | <ol style="list-style-type: none">7. Verify the female patient is under the supervision and care of a certified prescriber, and that she is enrolled or will be enrolled in the REMS Program prior to discharge through the processes and procedures established as a requirement of the REMS.
8. For females of reproductive potential: Verify the pregnancy testing is complete, and that the patient is counseled on the risk of embryo-fetal toxicity, the need to use reliable contraception, to get monthly pregnancy tests, and to inform the prescriber of a pregnancy immediately through the processes and procedures established as a requirement of the REMS Program. |
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| To maintain certification to dispense | <ol style="list-style-type: none">9. Have a new authorized representative enroll in the REMS Program by completing the Inpatient Pharmacy Enrollment Form if the authorized representative changes. |
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| At discharge | <ol style="list-style-type: none">10. Dispense no more than a 15-days' supply. |
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| At all times | <ol style="list-style-type: none">11. Report pregnancies to Actelion Pharmaceuticals, Ltd.
12. Not distribute, transfer, loan, or sell Opsumit expect to certified dispensers.
13. Maintain records that all processes and procedures are in place and are being followed.
14. Comply with audits carried out by the manufacturer or a third party acting on behalf of the manufacturer to ensure that all processes and procedures are in place and are being followed. |
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7. Wholesalers-distributors that distribute Opsumit must:

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| To be able to distribute | <ol style="list-style-type: none">1. Establish processes and procedures to ensure that the drug is distributed only to certified pharmacies.
2. Train all relevant staff involved in distribution on the Opsumit REMS Program requirements. |
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| At all times | <ol style="list-style-type: none">3. Distribute only to certified pharmacies.
4. Maintain records of drug distribution. |
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5. Comply with audits carried out by the manufacturer or a third party acting on behalf of the manufacturer to ensure that all processes and procedures are in place and are being followed.

Actelion Pharmaceuticals Ltd must provide training to healthcare providers who prescribe Opsumit.

The training includes the following educational materials: Prescribing Information and Prescriber and Pharmacy Guide. The training must be available online or by calling the REMS Program.

Actelion Pharmaceuticals Ltd must provide training to pharmacies that dispense Opsumit. The training includes the following educational material: Prescribing Information and Prescriber and Pharmacy Guide. The training must be available online or by calling the REMS Program.

To support REMS Program operations, Actelion Pharmaceuticals Ltd must:

1. Establish and maintain a REMS Program website, www.OpsumitREMS.com. The REMS Program website must include the capability 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.
2. Make the REMS Program website fully operational and all REMS materials available through the REMS Program website or coordinating center within 90 calendar days of REMS modification approval (06/10/2019).
3. Establish and maintain a REMS Program coordinating center for REMS participants at 1-866-228-3546.
4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the Opsumit REMS Program.
5. Ensure prescribers are able to certify by submitting a completed Prescriber Enrollment Form by fax and phone.
6. Ensure outpatient pharmacies are able to certify by contracting with the manufacturer and agreeing to comply with the requirements of the REMS Program.
7. Ensure inpatient pharmacies are able to certify by submitting a completed Inpatient Pharmacy Enrollment Form by fax and phone.
8. Ensure prescribers are able to report change in reproductive status by fax and phone.
9. Ensure prescribers are able to complete the patient enrollment process online, by phone, or by fax.
10. Ensure pharmacies are able to confirm patient enrollment, prescriber certification, and safe use conditions are met prior to dispensing of Opsumit online.
11. Ensure pharmacies are able to enroll as inpatient (including, but not limited to, pharmacies in hospitals, long-term care facilities, prisons, and state psychiatric units) or as outpatient pharmacies.
12. Ensure inpatient pharmacies are able to contact the coordinating center for assistance in obtaining up to a 15-day supply of drug for a specific inpatient while the inpatient pharmacy completes the certification process.
13. Provide the Prescriber Enrollment Form and Prescriber and Pharmacy Guide to prescribers who (1) attempt to prescribe Opsumit and are not yet certified or (2) inquire about how to become certified.

14. Notify certified pharmacies of a patient's change or misclassification in reproductive status within one business day of receipt of a completed Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form.
15. Provide certified prescribers access to the database of certified pharmacies and enrolled patients.
16. Provide certified pharmacies access to the database of certified prescribers and enrolled patients.

To ensure REMS participants' compliance with the REMS Program, Actelion Pharmaceuticals Ltd must:

17. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: Opsumit distribution and dispensing; certification of prescribers and pharmacies; enrolled patients; and audits of REMS pharmacies and wholesalers-distributors. These records must be readily available for FDA inspections.
18. Establish a plan for addressing noncompliance with REMS Program requirements.
19. Monitor prescribers, pharmacies, and wholesaler-distributors on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if noncompliance is identified, including de-certification.
20. Audit all certified outpatient pharmacies and wholesaler-distributors within 180 days after they become certified, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.
21. Audit all certified outpatient pharmacies, all wholesaler-distributors, the coordinating center for Opsumit, and at least 10% of certified inpatient pharmacies that have ordered Opsumit annually to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.
22. Take reasonable steps to improve operation of and compliance with the requirements in the Opsumit REMS Program based on monitoring and evaluation of the Opsumit REMS Program.

IV. REMS Assessment Timetable

Actelion Pharmaceuticals Ltd must submit REMS Assessments at 6 months and 1 year from the date of the initial REMS approval (10/18/2013), and then annually thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Actelion Pharmaceuticals Ltd must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the Opsumit REMS:

Enrollment Forms:

Prescriber:

1. [Prescriber Enrollment and Agreement Form](#)

Patient:

2. [Patient Enrollment and Consent Form](#)
3. [Patient Enrollment and Consent Form for VA use only](#)

Pharmacy:

4. [Inpatient Pharmacy Enrollment Form](#)

Training and Educational Materials

Prescriber:

5. [Prescriber and Pharmacy Guide](#)

Patient:

6. [Guide for Female Patients](#)

Pharmacy:

7. [Prescriber and Pharmacy Guide](#)

Patient Care Form

8. [Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#)

Other Materials

9. [REMS Program website \(www.OpsumitREMS.com\)](http://www.OpsumitREMS.com)

Opsumit® REMS Prescriber Enrollment and Agreement Form

Complete and fax this form to *Actelion Pathways®* at 1-866-279-0669 or call *Actelion Pathways* at 1-866-228-3546.

Contact *Actelion Pathways* via phone at 1-866-ACTELION (1-866-228-3546) for questions.



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Prescriber Information (please print)

First name _____ MI _____ Last name _____
Email address _____ NPI # _____ Professional designation _____
 MD DO PA NP

In the event you are unavailable, is there another person we can contact on your behalf? Yes No
If yes, please indicate.

Name _____ Phone _____

Office Practice/Clinic Information (please print)

Primary

Office practice/clinic name _____ Affiliated hospital _____
Specialty _____ Office contact name _____ Office contact phone _____
Office email address _____ Phone _____ Fax _____
Address _____ City _____
State _____ ZIP _____ Preferred method of contact _____
 Phone Fax Email

Secondary

Office practice/clinic name _____ Affiliated hospital _____
Specialty _____ Office contact name _____ Office contact phone _____
Office email address _____ Phone _____ Fax _____
Address _____ City _____
State _____ ZIP _____ Preferred method of contact _____
 Phone Fax Email

Opsumit REMS Prescriber Agreement

By signing below, you signify your understanding of the risks of Opsumit treatment and your obligation as an Opsumit prescriber to educate your female patients about the Opsumit REMS (Risk Evaluation and Mitigation Strategy), monitor them appropriately, and report any pregnancies to the Opsumit REMS.

Specifically, you attest to the following:

- I have read the Opsumit Prescribing Information and the *Prescriber and Pharmacy Guide* and agree to comply with the Opsumit REMS requirements
- I agree to enroll all female patients into the Opsumit REMS
- I will:
 - Determine the reproductive potential status of all female patients using the definitions provided in the *Prescriber and Pharmacy Guide*
 - Advise all females that Opsumit is only available through a restricted distribution program called the Opsumit REMS
 - Counsel Females of Reproductive Potential (FRP) on the risks of Opsumit, including the risk of serious birth defects, and review the *Guide for Female Patients* with the patient
 - Counsel the Pre-pubertal Female patients and parent/guardian on the risks of Opsumit, including the risk of serious birth defects, and review the *Guide for Female Patients* with the patient and parent/guardian
 - Counsel FRPs to immediately contact their healthcare provider if they miss a menstrual period or suspect pregnancy
 - Counsel Pre-pubertal Female patients and parent/guardian to immediately contact her healthcare provider if the patient begins to menstruate
 - Provide the *Guide for Female Patients* to all Females of Non-Reproductive Potential and instruct her to read it.
 - Verify the reproductive potential status annually for Pre-pubertal Females who are at least 8 years of age and older by submitting a *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form*
 - Order and review pregnancy tests for Females of Reproductive Potential prior to initiating treatment with Opsumit, monthly during treatment, and for 1 month after stopping treatment
 - Counsel FRPs to use reliable contraception during Opsumit treatment and for 1 month after stopping treatment; and discuss their medical options in the event of unprotected sexual intercourse or known or suspected contraceptive failure
 - Report any change or misclassification in reproductive potential status by submitting a *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* within 10 business days of becoming aware of the change
 - Counsel female patients who fail to comply with the Opsumit REMS requirements
 - Notify Actelion of any pregnancies at 1-866-ACTELION (1-866-228-3546)

Signature _____ Date _____

Please visit www.OpsumitREMS.com or call 1-866-ACTELION (1-866-228-3546) for more information about the Opsumit REMS.

Opsumit® REMS Patient Enrollment and Consent Form

Complete this form for ALL patients.

For immediate patient enrollment, please go to OpsumitREMS.com, or call *Actelion Pathways*® at 1-866-228-3546, or fax this completed form to 1-866-279-0669.

Contact *Actelion Pathways* at 1-866-228-3546 for questions.



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1 Patient Information (please print)

First name _____			Middle initial _____	Last name _____		Gender <input type="checkbox"/> Male <input type="checkbox"/> Female	
Birth date _____		Primary language _____		Email address _____			
Primary phone # _____		Alternate phone # _____		Best time to call _____			
Address _____			City _____	State _____	ZIP _____		
Legal guardian _____			Relationship _____		Phone # _____		
Emergency contact _____			Relationship _____		Phone # _____		

2 Female Patient Agreement

For All Females: I acknowledge that I understand that Opsumit is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS). I acknowledge that I have received and read the *Guide for Female Patients*.

For Females Who Can Get Pregnant: I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects. I have read the *Guide for Female Patients*. I understand that I will be contacted by Actelion and/or its agents and contractors to receive counseling and education on the Opsumit REMS and the risk of serious birth defects, the need to use reliable contraception during Opsumit treatment and for 1 month after stopping Opsumit treatment, the importance of not becoming pregnant, and to ensure that I have completed pregnancy testing: before I start Opsumit, monthly before each refill, and for 1 month after stopping Opsumit. I agree to be counseled each month by the certified pharmacy on the need to use reliable contraception during Opsumit treatment and for 1 month after stopping Opsumit. I understand that I must immediately contact my healthcare provider if I miss a menstrual period or suspect that I am pregnant; and that I may be contacted by Actelion and/or its agents and contractors to obtain information about my pregnancy, if I become pregnant.

For Pre-pubertal Females: I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects. I understand that I must immediately contact my healthcare provider if I get my menstrual period.

For Post-menopausal Females: I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects.

For Females with other medical reasons for permanent, irreversible infertility: I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects.

★ _____
(REQUIRED FOR ALL FEMALES) Patient or Parent/Guardian Signature Date

3 Prescriber Information (please print)

First name _____		Middle initial _____	Last name _____	
Address _____			City _____	
State _____	ZIP _____	Phone # _____	Opsumit Prescriber ID _____	
Fax # _____	NPI # _____	Office contact and email address _____		

4 Prescriber Authorization: If your patient is FEMALE, check correct female patient category (please see definitions of these terms on the following page):

REQUIRED (Check one category)

Female of Reproductive Potential

↳ If this patient is a Female of Reproductive Potential (which includes females who have undergone tubal sterilization), has a negative pregnancy test been completed prior to prescribing Opsumit?

Yes No

Female of Non-Reproductive Potential

Pre-pubertal Female

Post-menopausal Female

Female with other medical reasons for permanent, irreversible infertility

I certify that the above therapy ordered is medically necessary and agree to follow the "Prescriber Requirements" indicated on the second page of this form. Further, I hereby authorize Actelion and/or its designated representative(s), to act on my behalf for the limited purposes of providing this prescription to the certified specialty pharmacy for patient treatment purposes.

★ _____
(REQUIRED FOR ALL PRESCRIBERS) Prescriber Signature Date

Definitions of Reproductive Potential Status

Females of Reproductive Potential

- Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause (as defined below)
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal)
- For the purposes of this REMS, females who have undergone tubal sterilization are classified as females of reproductive potential

Females of Non-Reproductive Potential

- Pre-pubertal Females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential
- Post-menopausal Females: Females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy
- Females with other medical reasons for permanent, irreversible infertility

Prescriber Requirements

For All Females

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) that Opsumit is only available through a restricted distribution program under an FDA-required REMS
- I will evaluate the patient and agree to document any change or misclassification in reproductive potential status by submitting a *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* or contacting *Actelion Pathways*® at 1-866-228-3546 within 10 business days of becoming aware of the change

For Females of Reproductive Potential

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) on the risks of Opsumit, including the risk of serious birth defects, and that I have reviewed the *Guide for Female Patients* with the patient (and parent/guardian when appropriate)
- I will order and review pregnancy tests prior to initiation of Opsumit treatment, monthly during treatment, and for 1 month after stopping treatment in accordance with the Opsumit REMS

For Pre-pubertal Females

- I acknowledge that I have counseled the patient and parent/guardian on the risks of Opsumit, including the risk of serious birth defects, and that I have reviewed the *Guide for Female Patients* with the patient and parent/guardian
- I will evaluate the patient's reproductive potential status, verify reproductive potential status annually for Pre-pubertal Females who are at least 8 years of age and older, and agree to report any change or misclassification in reproductive potential status on a *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* or contact *Actelion Pathways* at 1-866-228-3546 within 10 business days of becoming aware of the change

5 Fax this form to 1-866-279-0669

Please visit www.OpsumitREMS.com or call 1-866-ACTELION (1-866-228-3546) for immediate patient enrollment, or for more information about the Opsumit REMS.

Opsumit® REMS Patient Enrollment and Consent Form

FOR VA USE ONLY

Complete this form for ALL patients. Fax this completed form to 1-866-279-0669. Contact Actelion Pathways® at 1-866-228-3546 for questions.

Note: Enrollment by phone and online enrollment are not available for VA patients.



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1 Patient Information (please print)

Form fields for Patient Information: First name, Middle initial, Last name, Gender (Male/Female), Birth date, Primary language, Email address, Primary phone #, Alternate phone #, Best time to call, Address, City, State, ZIP, Legal guardian, Relationship, Phone #, Emergency contact, Relationship, Phone #.

2 Female Patient Agreement

For All Females: I acknowledge that I understand that Opsumit is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS). I acknowledge that I have received and read the Guide for Female Patients. For Females Who Can Get Pregnant: I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects. For Pre-pubertal Females: I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects. For Post-menopausal Females: I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects. For Females with other medical reasons for permanent, irreversible infertility: I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects.

★ (REQUIRED FOR ALL FEMALES) Patient or Parent/Guardian Signature Date

3 Prescriber Information (please print)

Form fields for Prescriber Information: First name, Middle initial, Last name, Address, City, State, ZIP, Phone #, Fax #, NPI #, Opsumit Prescriber ID, Office contact and email address.

4 VA Pharmacy Information

Form fields for VA Pharmacy Information: VA Pharmacy, Address, City, State, ZIP, Contact, Phone #, Fax #.

5 Prescriber Authorization: If your patient is FEMALE, check correct female patient category (please see definitions of these terms on the following page):

REQUIRED (Check one category)

- Female of Reproductive Potential (with sub-option for tubal sterilization)
Female of Non-Reproductive Potential
Pre-pubertal Female
Post-menopausal Female
Female with other medical reasons for permanent, irreversible infertility

I certify that the above therapy ordered is medically necessary and agree to follow the "Prescriber Requirements" indicated on the second page of this form. Further, I hereby authorize Actelion and/or its designated representative(s), to act on my behalf for the limited purposes of providing this prescription to the certified specialty pharmacy for patient treatment purposes.

★ (REQUIRED FOR ALL PRESCRIBERS) Prescriber Signature Date

Definitions of Reproductive Potential Status

Females of Reproductive Potential

- Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause (as defined below)
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal)
- For the purposes of this REMS, females who have undergone tubal sterilization are classified as females of reproductive potential

Females of Non-Reproductive Potential

- Pre-pubertal Females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential
- Post-menopausal Females: Females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy
- Females with other medical reasons for permanent, irreversible infertility

Prescriber Requirements

For All Females

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) that Opsumit is only available through a restricted distribution program under an FDA-required REMS
- I will evaluate the patient and agree to document any change or misclassification in reproductive potential status by submitting an *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* or contacting *Actelion Pathways*® at 1-866-228-3546 within 10 business days of becoming aware of the change

For Females of Reproductive Potential

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) on the risks of Opsumit, including the risk of serious birth defects, and that I have reviewed the *Guide for Female Patients* with the patient (and parent/guardian when appropriate)
- I will order and review pregnancy tests prior to initiation of Opsumit treatment, monthly during treatment, and for 1 month after stopping treatment in accordance with the Opsumit REMS

For Pre-pubertal Females

- I acknowledge that I have counseled the patient and parent/guardian on the risks of Opsumit, including the risk of serious birth defects, and that I have reviewed the *Guide for Female Patients* with the patient and parent/guardian
- I will evaluate the patient's reproductive potential status, verify reproductive potential status annually for Pre-pubertal Females who are at least 8 years of age and older, and agree to report any change or misclassification in reproductive potential status on an *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* or contact *Actelion Pathways* at 1-866-228-3546 within 10 business days of becoming aware of the change

6 Fax this form to 1-866-279-0669

Please visit www.OpsumitREMS.com or call 1-866-ACTELION (1-866-228-3546) for more information about the Opsumit REMS.

Opsumit® REMS Inpatient Pharmacy Enrollment Form

Complete and fax this form to *Actelion Pathways*® at 1-866-279-0669 or call *Actelion Pathways* at 1-866-228-3546.

Contact *Actelion Pathways* at 1-866-ACTELION (1-866-228-3546) for questions.



H02201512

Due to the risk of embryo-fetal toxicity for female patients, Opsumit is available only through a restricted program called the Opsumit REMS (Risk Evaluation and Mitigation Strategy). In order for inpatients to receive Opsumit, females, as well as inpatient pharmacies that wish to stock this product, must enroll in the Opsumit REMS and agree to comply with the requirements of the program. An Authorized Representative must complete and submit this form on behalf of the inpatient pharmacy, or call *Actelion Pathways* at 1-866-228-3546 to enroll.

Inpatient pharmacy information (please print)

Name

Hospital Nursing home Hospice Asylum/Mental facility Assisted Living Prison Rehabilitation

Other (please specify): _____

Identification (please complete one of the following):

Health Industry Number (HIN #) _____ National Provider Identifier (NPI #) _____

Other identifier: _____

Address

City _____ State _____ ZIP _____

Phone # _____ Fax # _____

Ship to address (if different from above)

Address

City _____ State _____ ZIP _____

Phone # _____ Fax # _____

Authorized Representative information (please print)

Title:

Hospital pharmacist Head of Pharmacy and Therapeutics (P&T) committee

Other title: _____

Name

Authorized Representative phone #

Fax #

Authorized Representative email

Authorized Representative consent

This inpatient pharmacy will:

- Put processes and procedures in place to ensure the Opsumit REMS requirements are met
- Dispense only to those patients under the supervision and care of a healthcare provider who is enrolled in the Opsumit REMS
- Dispense to a female patient only after she has been enrolled in the Opsumit REMS or if she will be enrolled prior to discharge from this healthcare facility. A female who has not been enrolled by the certified prescriber will not have access to Opsumit in the outpatient setting until such time that registration has been completed
- Dispense no more than a fifteen- (15-) day temporary supply of Opsumit upon discharge of any patient
- Notify Actelion Pharmaceuticals US, Inc. ("Actelion") or FDA if any patient becomes pregnant during Opsumit treatment
- Not transfer Opsumit to any pharmacy, practitioner, or any healthcare setting not certified by *Actelion Pathways*
- Develop a process to track compliance with the conditions above and provide information about its compliance to Actelion
- Re-enroll in the Opsumit REMS if the pharmacy designates a new authorized representative

I attest that I have read the Opsumit Prescribing Information and *Prescriber and Pharmacy Guide* available at www.OpsumitREMS.com.

I will ensure training of dispensing staff on the Opsumit REMS procedures and materials, including the *Prescriber and Pharmacy Guide* prior to dispensing Opsumit.

I agree that this pharmacy may be audited by the FDA, Actelion, or a designated third-party.

Note: If your inpatient pharmacy needs Opsumit and is not enrolled in the Opsumit REMS, contact *Actelion Pathways* at 1-866-228-3546 for assistance in obtaining a 15-day supply of Opsumit for a specific inpatient while initiating enrollment.

Signature

Date

Please visit www.OpsumitREMS.com or call 1-866-ACTELION (1-866-228-3546) for more information about the Opsumit REMS.

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Reference ID: 4586229

Prescriber and Pharmacy Guide for the Opsumit[®] REMS

(Risk Evaluation and Mitigation Strategy)



Opsumit.
macitentan tablets 10 mg

*Please see accompanying full Prescribing Information,
including **BOXED WARNING** for embryo-fetal toxicity.*

ACTELION
Pathways[®]

Introduction to Opsumit® (macitentan)

Indication

Opsumit is an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH.

Effectiveness was established in a long-term study in PAH patients with predominantly WHO Functional Class II-III symptoms treated for an average of 2 years. Patients had idiopathic and heritable PAH (57%), PAH caused by connective tissue disorders (31%), and PAH caused by congenital heart disease with repaired shunts (8%).

Risk of embryo-fetal toxicity

Opsumit is contraindicated in females who are pregnant. Opsumit may cause fetal harm when administered to a pregnant woman. Opsumit was consistently shown to have embryo-fetal toxicity effects when administered to animals. If Opsumit is used during pregnancy, advise the patient of the potential risk to a fetus. To prevent pregnancy, females of reproductive potential must use reliable contraception during treatment and for one month after stopping Opsumit. Patients must not become pregnant while taking Opsumit.

Opsumit REMS (Risk Evaluation and Mitigation Strategy)

Due to the risk of embryo-fetal toxicity, Opsumit is only available to females through a restricted distribution program required by the FDA called the Opsumit REMS (**R**isk **E**valuation and **M**itigation **S**trategy).

The goal of the Opsumit REMS is to mitigate the risk of embryo-fetal toxicity associated with Opsumit by:

1. Ensuring prescribers are educated on the following:
 - the risks of embryo-fetal toxicity
2. Ensuring prescribers are educated on and adhere to the following:
 - counseling patients about these risks and the need for monthly monitoring
 - enrolling patients in the Opsumit REMS
 - monitoring patients at baseline and monthly
3. Ensuring that pharmacies are educated on the following:
 - the risks of embryo-fetal toxicity
4. Ensuring that pharmacies are educated on and adhere to the following:
 - confirming that the appropriate patient monitoring and counseling has occurred before dispensing Opsumit
5. Ensuring that patients are informed about:
 - the risks of embryo-fetal toxicity
 - appropriate baseline and monthly patient monitoring
 - appropriate contraception

*Please see accompanying full Prescribing Information, including **BOXED WARNING** for embryo-fetal toxicity.*

Opsumit REMS overview

- All healthcare providers must enroll in the Opsumit REMS and comply with the requirements to prescribe Opsumit
- All female patients must enroll in the Opsumit REMS to receive Opsumit
- Prescribers must counsel Females of Reproductive Potential and Pre-pubertal Females of Non-Reproductive Potential about the risks of Opsumit, including the risk of serious birth defects
- Prescribers must order and review pregnancy testing for Females of Reproductive Potential prior to initiation of treatment, monthly during treatment, and one month after stopping treatment
- Prescribers must report any change or misclassification in a female's reproductive potential status to the Opsumit REMS
- Definitions of Reproductive Potential Status
 - Females of Reproductive Potential
 - Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause (as defined below)
 - For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal)
 - For the purposes of this REMS, females who have undergone tubal sterilization are classified as females of reproductive potential
 - Females of Non-Reproductive Potential
 - Pre-pubertal Females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential
 - Post-menopausal Females: Females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy
 - Females with other medical reasons for permanent, irreversible infertility

- For Females of Reproductive Potential:
 - Pregnancy must be ruled out prior to drug initiation, monthly during treatment, and one month after stopping treatment
 - She must agree to be contacted by *Actelion Pathways*® if she becomes pregnant either while on Opsumit® or within one month of treatment discontinuation
- Only pharmacies certified in the Opsumit REMS can dispense Opsumit to outpatients
- Only inpatient pharmacies that are certified in the Opsumit REMS may stock Opsumit for inpatient use

Summary of Opsumit REMS requirements for female patients

All **prescribers** must be enrolled in the Opsumit REMS. To become enrolled, a healthcare provider must complete a *Prescriber Enrollment and Agreement Form* agreeing to follow the Opsumit REMS requirements. This form must be submitted to the Opsumit REMS, by faxing the completed form to 1-866-279-0669 **or** by calling *Actelion Pathways* at 1-866-228-3546.

All **females** must be enrolled in the Opsumit REMS in order to receive Opsumit. To become enrolled, a patient must complete a *Patient Enrollment and Consent Form* with her prescriber. This form must be submitted to the Opsumit REMS, and can be completed online at OpsumitREMS.com, **or** by calling *Actelion Pathways* at 1-866-228-3546, **or** by faxing the completed form to 1-866-279-0669.

Prescribers must determine whether the patient is a Female of Reproductive Potential or a Female of Non-Reproductive Potential (Pre-pubertal Female, Post-menopausal Female, or a female with other medical reasons for permanent, irreversible infertility). **This category must be documented on the *Patient Enrollment and Consent Form*.** (See definitions of Reproductive Potential Status.)

Based on whether the patient is a Female of Reproductive Potential or a Female of Non-Reproductive Potential (Pre-pubertal Female, Post-menopausal Female, or a female with other medical reasons for permanent, irreversible infertility), the prescriber must perform certain actions before initiating treatment, during treatment, and after the patient stops taking Opsumit.

*Please see accompanying full Prescribing Information, including **BOXED WARNING** for embryo-fetal toxicity.*

Summary of Opsumit® REMS requirements for female patients (continued)

Requirement	Females of Reproductive Potential	Females of Non-Reproductive Potential	
		Pre-pubertal	Post-menopausal or other medical reasons for permanent, irreversible infertility
Prescriber enrolls female patients into Opsumit REMS	●	●	●
Prescriber counsels with <i>Guide for Female Patients</i>	●	●*	●
Prescriber must order and review pregnancy tests prior to initiation of treatment, monthly during treatment, and for 1 month after stopping treatment	●		
Prescriber must verify reproductive status annually in Pre-pubertal patients 8 years of age or older by completing the <i>Opsumit REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form</i>		●	
Prescriber must complete the <i>Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form</i> upon becoming aware of any change or misclassification in reproductive potential status within 10 business days of awareness	●	●	●

*Counsel Pre-pubertal Female patient and/or parent/guardian.

Prescriber's role in the Opsumit REMS

Healthcare providers must complete the following steps in the Opsumit REMS:

1. **Read** the Opsumit Prescribing Information and this guide to understand the risks of Opsumit and to learn about the Opsumit REMS
2. **Complete** a *Prescriber Enrollment and Agreement Form*
3. **Determine** the reproductive potential of female patients
4. **Educate and counsel** all female patients about the risks of Opsumit
5. **Enroll** female patients into the Opsumit REMS by completing an *Patient Enrollment and Consent Form*
6. **Check** patient's pregnancy status (if patient is a Female of Reproductive Potential)
7. **Monitor** pregnancy and reproductive potential status for female patients throughout treatment

The next section provides specific information on each step:

1. **Read the Opsumit Prescribing Information and this guide to understand the risks of Opsumit and to learn about the Opsumit REMS**
 - Prescribers must understand the risks of Opsumit and become familiar with the Opsumit REMS
2. **Complete a *Prescriber Enrollment and Agreement Form***
 - You can download the *Prescriber Enrollment and Agreement Form* from OpsumitREMS.com and fax it to Actelion Pathways® at 1-866-279-0669 **or** you may enroll by calling Actelion Pathways at 1-866-228-3546. Actelion Pathways administers the Opsumit REMS. After providing your enrollment by phone you will receive a pre-populated form by fax to sign and fax to 1-866-279-0669.
 - By signing the form, you attest to understanding the risks of Opsumit and agree to comply with the Opsumit REMS
3. **Determine the reproductive potential for female patients**
 - Prescribers should identify female patients (captured on the *Patient Enrollment and Consent Form*) as belonging to one of the following categories:
 - Female of Reproductive Potential (FRP)

or

 - Female of Non-Reproductive Potential (FNRP) (choose one of the options below)
 - Pre-pubertal Female of Non-Reproductive Potential
 - Post-menopausal Female of Non-Reproductive Potential
 - Female with other medical reasons for permanent, irreversible infertility

Definitions are provided in the section "Opsumit REMS Overview."

Please see accompanying full Prescribing Information, including **BOXED WARNING** for embryo-fetal toxicity.

4. **Educate and counsel** all female patients about the risks of Opsumit®

- For all females, prescribers must:
 - Advise the patient that Opsumit is only available through a restricted distribution program called the Opsumit REMS
 - Educate and counsel patients about the risks of Opsumit
- For Females of Reproductive Potential (FRP), prescribers must:
 - Review with her the *Guide for Female Patients*
 - Educate her about the risk of embryo-fetal toxicity; the need to use reliable contraception during Opsumit treatment and for one month following treatment discontinuation; and her need to consider medical options in the event of unprotected sexual intercourse or known or suspected contraception failure
 - Advise the patient of the requirement for initial and monthly pregnancy tests to confirm they are not pregnant, so they can begin and continue to receive Opsumit
 - Counsel her to immediately contact her healthcare provider if she misses a menstrual period or suspects she is pregnant
 - Counsel her that she must agree to be contacted prior to each shipment to confirm that a pregnancy test has been completed
- For Females of Non-Reproductive Potential (FNRP)
 - For a Post-menopausal Female or a female with other medical reasons for permanent, irreversible infertility, prescribers must provide the *Guide for Female Patients* and instruct her to read it
 - For Pre-pubertal Females, prescribers must:
 - Review with her and her parent/guardian the *Guide for Female Patients*
 - Educate her and her parent/guardian about the risk of serious birth defects
 - Counsel her and her parent/guardian to immediately contact her healthcare provider if she gets her menstrual period
- Prescribers must counsel any patient who fails to comply with the program requirements

5. **Enroll** female patients into the Opsumit REMS by completing the *Patient Enrollment and Consent Form*

- Enroll a patient **online**
 - For immediate patient enrollment, please go to OpsumitREMS.com
 - Confirm patient has agreed to comply with program requirements and has signed the form where indicated
 - Patients can sign electronically at the time of enrollment by typing their name into the signature box, or signing with their finger or stylus on touchscreen devices. Patients can also provide their email address to provide an electronic signature later. Print the form and keep with the patient's records
- Enroll a patient **by fax** using the printed form
 - Download the *Patient Enrollment and Consent Form* from OpsumitREMS.com
 - Confirm patient has agreed to comply with program requirements and has signed the form where indicated
 - Fax the completed form to *Actelion Pathways*® at 1 866-279-0669. *Actelion Pathways* administers the Opsumit REMS
 - Keep the original form with the patient's records
- Enroll a patient by **calling** *Actelion Pathways* at 1-866-228-3546
 - Confirm patient has agreed to comply with program requirements and provided their verbal consent by calling *Actelion Pathways* at 1-866-228-3546
 - Sign the pre-populated form faxed by *Actelion Pathways* and fax the signed and completed form to *Actelion Pathways* at 1 866-279-0669
 - Keep the signed form with the patient's records

Note: Enrollment by phone and online enrollment are not available for VA patients.

6. **Check** patients' pregnancy status (for Females of Reproductive Potential)

- Order and review pregnancy tests for the patient:
 1. Prior to initiating treatment
 2. Monthly during treatment
 3. One (1) month after stopping treatment

7. **Monitor** patients throughout treatment

- For FRPs, prescribers must:
 - Order and review pregnancy tests monthly during treatment with Opsumit® and for one month after stopping treatment
 - Notify the patient and Actelion if a patient’s pregnancy test is positive
 - Monitor patients’ reproductive status during treatment with Opsumit and report any changes or misclassifications to the Opsumit REMS by completing and submitting the *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* within 10 business days of becoming aware of the change **or** by contacting *Actelion Pathways*® at 1-866-228-3546
- For FNRPs, prescribers must:
 - Monitor patients’ reproductive status during treatment with Opsumit and report any changes or misclassifications to the Opsumit REMS by completing and submitting the *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* **or** by contacting *Actelion Pathways* at 1-866-228-3546 within 10 business days of becoming aware of the change
 - For each Pre-pubertal Female who is at least 8 years of age and older, annually verify and report the reproductive status by completing and submitting the *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* **or** by contacting *Actelion Pathways* at 1-866-228-3546

Contraceptive options for FRPs

All FRPs must use reliable contraception during Opsumit® treatment and for one month after stopping treatment. They should also have contraceptive counseling with either the prescriber or another designated healthcare provider trained in contraceptive counseling. Please refer to the following table for a complete list of acceptable contraceptive methods. A similar table can be found in the *Guide for Female Patients* and should be used to discuss acceptable birth control options with patients. The patient should be instructed to select one of the options listed.

- Educate and counsel females of reproductive potential about medical options in the event of unprotected sex or known or suspected contraceptive failure
- Remind patients to report any delay in getting a period or any other reason of suspected pregnancy during treatment to you immediately
- If pregnancy is suspected for any reason, a pregnancy test must be performed
- The prescriber must notify Actelion at 1-866-228-3546 of any pregnancies that occur during treatment or within 1 month of discontinuation

Contraceptive options for Females of Reproductive Potential

Acceptable birth control options

Option 1 One method from this list:	OR	Option 2 One method from this list:	OR	Option 3 One method from this list:	OR	Option 4 One method from this list:
Standard intrauterine device (Copper T 380A IUD) Intrauterine system (LNg 20 IUS; progesterone IUS) Progesterone implant Tubal sterilization		Estrogen and progesterone oral contraceptives ("the pill") Estrogen and progesterone transdermal patch Vaginal ring Progesterone injection		Diaphragm with spermicide Cervical cap with spermicide PLUS One method from this list: Male condom		Partner's vasectomy PLUS One method from this list: Male condom Diaphragm with spermicide Cervical cap with spermicide Estrogen and progesterone oral contraceptives ("the pill") Estrogen and progesterone transdermal patch Vaginal ring Progesterone injection
		PLUS One method from this list: Male condom Diaphragm with spermicide Cervical cap with spermicide				

Please see accompanying full Prescribing Information, including **BOXED WARNING** for embryo-fetal toxicity.

Certified pharmacies

Due to the risk of serious birth defects, Opsumit® is only available via a network of certified pharmacies. For a list of certified pharmacies please call *Actelion Pathways*® at 1-866-228-3546.

Actelion Pathways is Actelion's services and support program that administers the Opsumit REMS.

OUTPATIENT PHARMACY CERTIFICATION:

Only a limited number of certified pharmacies will dispense Opsumit for outpatients. Prior to dispensing Opsumit to any female, the pharmacy will confirm that the female and the prescriber who wrote the prescription are enrolled in the Opsumit REMS. If either the female or prescriber is not enrolled, Opsumit will not be dispensed.

Females of Reproductive Potential and Pre-pubertal Females will only be able to get a 30-day supply of Opsumit at one time. The *Opsumit Medication Guide* will be provided to all patients each time Opsumit is dispensed.

Females of Reproductive Potential will be contacted each month by the pharmacy to arrange dispensing of Opsumit. The pharmacy will:

- Ask if she has had a pregnancy test within the last month
- Counsel her on the need to use reliable contraception during Opsumit treatment and for one month after stopping treatment
- Counsel her to inform her prescriber immediately if she misses a menstrual period or suspects that she may be pregnant, or if her reproductive status changes

For Pre-pubertal Females, pharmacies will:

- Counsel her to inform her prescriber immediately if her reproductive status changes

INPATIENT PHARMACY CERTIFICATION:

Inpatient pharmacies must agree to follow the REMS requirements, including:

- Dispense only to those patients under the supervision and care of a healthcare provider who is enrolled in the Opsumit REMS
- Dispense to a female patient only after she has been enrolled in the Opsumit REMS or if she will be enrolled prior to discharge from this healthcare facility. A female who has not been enrolled by the certified prescriber will not have access to Opsumit in the outpatient setting until such time that registration has been completed
- Dispense no more than a fifteen- (15-) day temporary supply of Opsumit upon discharge of any patient
- Not transfer Opsumit to any pharmacy, practitioner, or healthcare setting not certified by *Actelion Pathways*

To be certified in the Opsumit REMS, an authorized representative of the inpatient pharmacy must:

- Read the Opsumit Prescribing Information and *Prescriber and Pharmacy Guide*
- Put processes and procedures in place to ensure the Opsumit REMS requirements are met
- Ensure training of dispensing staff on the Opsumit REMS procedures and materials, including the *Prescriber and Pharmacy Guide* prior to dispensing Opsumit
- Enroll in the Opsumit REMS if the inpatient pharmacy designates a new authorized representative by completing, signing, and submitting a new ***Inpatient Pharmacy Enrollment Form*** as soon as the designated authorized representative changes
- Notify Actelion Pharmaceuticals US, Inc. (“Actelion”) or FDA if any patient becomes pregnant during Opsumit treatment
- Develop a process to track compliance with the conditions above and provide information about its compliance to Actelion
- Agree that this pharmacy may be audited by the FDA, Actelion, or a designated third party
- Agree to follow the REMS requirements by completing and submitting an *Inpatient Pharmacy Enrollment Form* to the Opsumit REMS
 - Authorized representatives can complete the *Inpatient Pharmacy Enrollment Form*:
 - By faxing the printed form to 1-866-279-0669
 - By calling the Opsumit REMS at 1-866-228-3546

If an inpatient pharmacy needs Opsumit and is not enrolled in the Opsumit REMS, the inpatient pharmacy can contact *Actelion Pathways* at 1-866-228-3546 for assistance in obtaining a 15-day supply of Opsumit for a specific inpatient while initiating enrollment.

To learn more about the serious risks associated with Opsumit, please refer to the full Prescribing Information including BOXED WARNING, the *Prescriber and Pharmacy Guide*, and the *Guide for Female Patients*. These materials are available at www.OpsumitREMS.com.

If you have questions about Opsumit REMS program enrollment, or if you would like more information about Opsumit, you can reach *Actelion Pathways* by calling toll-free at 1-866-ACTELION (1-866-228-3546).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

*Please see accompanying full Prescribing Information, including **BOXED WARNING** for embryo-fetal toxicity.*



The Opsumit® REMS is administered by *Actelion Pathways*®.

You can reach *Actelion Pathways* by calling toll free
1-866-ACTELION (1-866-228-3546).

For more information about the Opsumit REMS,
please visit www.OpsumitREMS.com

*Please see accompanying full Prescribing Information,
including **BOXED WARNING** for embryo-fetal toxicity.*



Opsumit[®] REMS (Risk Evaluation and Mitigation Strategy) Guide for Female Patients

Information to help you throughout your treatment with Opsumit



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What is Opsumit?

Opsumit is a prescription medicine used to treat pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs.

Opsumit can improve your ability to exercise, improve some of your symptoms, and help slow down the progression of your disease. Opsumit can also lower your chance of being hospitalized for PAH.

It is not known if Opsumit is safe and effective in children.

What are the serious risks of Opsumit?

Opsumit can cause **serious birth defects** if taken during pregnancy. Women must not be pregnant:

- When they start taking Opsumit,
 - While taking Opsumit, or
 - Within one month of stopping Opsumit
-

What is the Opsumit REMS (Risk Evaluation and Mitigation Strategy)?

The Opsumit REMS is a program to tell patients and healthcare providers about the risk of serious birth defects when taking Opsumit. This program is required by the Food and Drug Administration (FDA). All females must enroll in the Opsumit REMS to receive Opsumit. REMS stands for **R**isk **E**valuation and **M**itigation **S**trategy.

How do I enroll in the Opsumit® REMS?

There are several steps you must take:

1. Read this *Guide for Females Patients*. Ask your healthcare provider any questions you have about taking Opsumit and the Opsumit REMS
2. Make sure you understand:
 - The benefits and risks of Opsumit
 - How to enroll and take part in the Opsumit REMS
3. Complete and sign the *Patient Enrollment and Consent Form* with your healthcare provider. Your healthcare provider will complete most of the enrollment form for you and will send the form to *Actelion Pathways*®. *Actelion Pathways* runs the Opsumit REMS. For additional information please see the next section titled **What are the Opsumit REMS requirements for me?**

What are the Opsumit REMS requirements for me?

Females Who **Cannot** Get Pregnant

You are considered a female who is **not** able to get pregnant if you:

- Have not yet entered puberty, **or**
- Do not have a uterus, **or**
- Have gone through menopause (Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed.), **or**
- Are infertile for other medical reasons and this infertility is permanent and cannot be reversed.

To receive Opsumit, you must:

- Enroll in the Opsumit REMS by completing the *Patient Enrollment and Consent Form*
 - Your prescriber will help you complete this form
 - You must understand your requirements in the Opsumit REMS and provide your signature:
 - electronically (if enrolling online), **or**
 - on the form itself (if enrolling by paper), **or**
 - by calling *Actelion Pathways* to provide your verbal consent (if enrolling by phone)
- Tell your prescriber if you become pregnant or your ability to become pregnant changes
- Receive counseling from your prescriber on the risk of serious birth defects (only if you are premenopausal)

- Be monitored every year to see if your ability to become pregnant changes and tell your prescriber if your ability to become pregnant changes (only if you are over the age of 8)

Note:

- Enrollment by phone and online enrollment are not available for VA patients
- If you are a parent or caregiver of a female child who started taking Opsumit® before reaching puberty, you should check your child regularly to see if she is developing signs of puberty. Tell your doctor right away if you notice that she is developing breast buds or pubic hair. Your doctor should decide if your child has reached puberty. Your child may reach puberty before having her first menstrual period

Females Who **Can** Get Pregnant

You are considered a female who can get pregnant if you:

- Have entered puberty, even if you have not started your period, and
- Have a uterus, and
- Have not gone through menopause (have not had a period for at least 12 months for natural reasons, or have had your ovaries removed)

To receive Opsumit, you must:

- Enroll in the Opsumit REMS by completing the *Patient Enrollment and Consent Form*
 - Your prescriber will help you complete this form
 - You must understand your requirements in the Opsumit REMS and provide your signature:
 - electronically (if enrolling online), **or**
 - on the form itself (if enrolling by paper), **or**
 - by calling *Actelion Pathways* to provide your verbal consent (if enrolling by phone)
- Enrollment by phone and online enrollment are not available for VA patients
- Have a negative pregnancy test:
 - before starting Opsumit,
 - each month for as long as you are being treated with Opsumit, and
 - for one month after you stop taking Opsumit

Your healthcare provider will order the pregnancy tests for you. You may not receive your Opsumit refill on time if you do not confirm with the pharmacy that you have had your monthly pregnancy test

- Use reliable birth control at all times when taking Opsumit and for one month after stopping Opsumit. Your birth control options are listed on page 5
- Do not have unprotected sex

Talk to your healthcare provider right away if you have unprotected sex, if you think your birth control has failed, or if you think you are pregnant. If so, your healthcare provider may discuss medical options with you (e.g., emergency contraception). Do not wait until your next appointment to tell your healthcare provider if you miss your menstrual period or if you think you are pregnant.

Opsumit is not available at your local pharmacy. You must receive Opsumit through a certified pharmacy (sometimes called a specialty pharmacy).

Your pharmacy will call you every month to ask if you have completed a pregnancy test before shipping your Opsumit to your home or another shipping address you choose.

What are my birth control options?

If you are a female who can get pregnant, your healthcare provider will talk with you about your birth control options before starting Opsumit. Ask your healthcare provider if you have any questions. Tell your healthcare provider if you want to change your birth control.

You must choose one of the 4 options listed below. More than one birth control method might be needed every time you have sex.

Acceptable birth control options

Option 1 One method from this list:	OR	Option 2 One method from this list:	OR	Option 3 One method from this list:	OR	Option 4 One method from this list:
Standard intrauterine device (Copper T 380A IUD) Intrauterine system (LNg 20 IUS: progesterone IUS) Progesterone implant Tubal sterilization		Estrogen and progesterone oral contraceptives ("the pill") Estrogen and progesterone transdermal patch Vaginal ring Progesterone injection		Diaphragm with spermicide Cervical cap with spermicide PLUS One method from this list: Male condom		Partner's vasectomy PLUS One method from this list: Male condom Diaphragm with spermicide Cervical cap with spermicide Estrogen and progesterone oral contraceptives ("the pill") Estrogen and progesterone transdermal patch Vaginal ring Progesterone injection

How will I receive Opsumit®?

Opsumit is available only through a certified pharmacy (sometimes called a specialty pharmacy).

- *Actelion Pathways*® provides support and services that help patients with their PAH medicines. Once you are enrolled, a Patient Case Manager will work with you to get your Opsumit prescription filled by a pharmacy
- Before your first prescription is filled, the pharmacy will call you to schedule a shipment of Opsumit that will come right to your home
- The *Opsumit Medication Guide* will be included in the package
- Read the *Opsumit Medication Guide* each time you receive it. Important information may have been added or changed

For a list of certified pharmacies, please call *Actelion Pathways* at **1-866-ACTELION (1-866-228-3546)**.

Your steps to treatment with Opsumit®

Use this helpful checklist to get started with Opsumit and to stay on track during your treatment.

FIRST:

- Review the *Guide for Female Patients* with your healthcare provider
- Make sure you understand the risks and benefits of taking Opsumit
- Go for your pregnancy test
- Enroll in the Opsumit REMS

NEXT:

- Expect a call from your Patient Case Manager. He or she will help you get your Opsumit prescription filled by one of the certified pharmacies
- Expect a call from the pharmacy to schedule your first shipment

EVERY MONTH:

- Read the *Opsumit Medication Guide* that comes with every shipment
- Use reliable birth control method(s) agreed upon with your healthcare provider—during treatment and for one month after you stop taking Opsumit
- Complete the monthly pregnancy test ordered by your healthcare provider
- Expect your pharmacy to call you every month to ask if you had a pregnancy test in the last month before it reorders your Opsumit. The refill may not be done on time if you've not had your pregnancy test
- Do not get pregnant. Tell your healthcare provider right away if you:
 - Have unprotected sex
 - Think that your birth control failed
 - Miss a menstrual period
 - Think you are pregnant



The Opsumit® REMS is administered by *Actelion Pathways*®.

You can reach *Actelion Pathways* by calling toll free at 1-866-ACTELION (1-866-228-3546).

For more information about the Opsumit REMS, please visit www.OpsumitREMS.com.

*Please see accompanying full Prescribing Information, including **BOXED WARNING** for birth defects.*



Opsumit® REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form

**NOTE: THIS FORM SHOULD NOT BE USED TOGETHER WITH THE ENROLLMENT FORM.
USE IT ONLY TO REPORT A CHANGE IN REPRODUCTIVE STATUS OR FOR PRE-PUBERTAL ANNUAL VERIFICATION.**

Complete this form to:

- 1) Change the reproductive status of any female patient within 10 business days of awareness of the change in reproductive status.
- 2) Complete the annual verification of the reproductive potential status for pre-pubertal females 8 years of age or older.

To report a change in reproductive status for a female patient or to verify that a patient remains pre-pubertal, you may fax this form to 1-866-279-0669 or call *Actelion Pathways®* at 1-866-228-3546.

Note: Prescribers must report a change within 10 business days of awareness of the change in reproductive status.

Patient Information (please print)

Patient Opsumit ID _____

First name _____ MI _____ Last name _____

Address _____

City _____ State _____ ZIP _____

Birth date _____ Phone _____

Prescriber Information (please print)

First name _____ MI _____ Last name _____

NPI # _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Opsumit Prescriber ID (if available) _____

Office contact and email address (optional) _____

Definitions of Reproductive Potential Status

Females of Reproductive Potential

- Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause (as defined below)
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal)
- For the purposes of this REMS, females who have undergone tubal sterilization are classified as females of reproductive potential

Females of Non-Reproductive Potential

- Pre-pubertal females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential
- Post-menopausal females: Females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy
- Females with other medical reasons for permanent, irreversible infertility

Select the most appropriate reason for submitting this form. (For reference, please see the Definitions of Reproductive Potential Status)

Change in Status

• Based on definitions of reproductive potential status, patient is (please check one):

- Female of Reproductive Potential
- Female of Non-Reproductive Potential – Patient is pre-pubertal
- Female of Non-Reproductive Potential – Patient is post-menopausal
- Female of Non-Reproductive Potential – Other medical reasons for permanent, irreversible infertility

• Reason for change in classification (please check one):

- Physiological transition
- Medical/surgical (please specify): _____
- Other (please specify): _____

• Annual Verification

- Patient remains a Pre-pubertal Female (8 years of age or older)

Prescriber Acknowledgement (REQUIRED)

By signing, I certify that the patient's reproductive status as noted above is accurate, and that I will comply with the REMS requirements for my patient's reproductive potential status.

Prescriber signature _____

Title (MD/PA/NP, etc.) _____

Date _____

Please visit www.OpsumitREMS.com or call 1-866-ACTELION (1-866-228-3546) for more information about the Opsumit REMS.

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Reference ID: 4586229



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Opsumit REMS (Risk Evaluation and Mitigation Strategy)

A Risk Evaluation and Mitigation Strategy (REMS) is a program required by the Food and Drug Administration (FDA) to manage serious risks associated with a drug product.

The Opsumit REMS is for females only. Male patients are not required to enroll in the Opsumit REMS.

The goal of the Opsumit REMS is to mitigate the risk of embryo-fetal toxicity associated with Opsumit by:

1. Ensuring prescribers are educated on the following:
 - the risks of embryo-fetal toxicity
2. Ensuring prescribers are educated on and adhere to the following:
 - counseling patients about these risks and the need for monthly monitoring
 - enrolling patients in the Opsumit REMS
 - monitoring patients at baseline and monthly
3. Ensuring that pharmacies are educated on the following:
 - the risks of embryo-fetal toxicity
4. Ensuring that pharmacies are educated on and adhere to the following:
 - confirming that the appropriate patient monitoring and counseling has occurred before dispensing Opsumit
5. Ensuring that patients are informed about:
 - the risks of embryo-fetal toxicity
 - appropriate baseline and monthly patient monitoring
 - appropriate contraception

Prescribers

For Prescriber Information
[Click Here](#)

Female Patients

For Patient Information
[Click Here](#)

Opsumit REMS Overview:

- All healthcare providers must enroll in the Opsumit REMS and comply with requirements to prescribe Opsumit
- All female patients must be enrolled in the Opsumit REMS to receive Opsumit
- Females of Reproductive Potential and Pre-pubertal Females of Non-Reproductive Potential are required to be counseled on the risks of Opsumit
- Females of Reproductive Potential are required to get monthly pregnancy testing
- A limited number of certified pharmacies will dispense Opsumit for outpatients. They must enroll in the Opsumit REMS and agree to the REMS requirements
- Pharmacies that supply inpatient use of Opsumit must also be certified by enrolling in the Opsumit REMS and agreeing to the REMS requirements

Opsumit[®] is an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH.

Effectiveness was established in a long-term study in PAH patients with predominantly WHO Functional Class II-III symptoms treated for an average of 2 years. Patients had idiopathic and heritable PAH (57%), PAH caused by connective tissue disorders (31%), and PAH caused by congenital heart disease with repaired shunts (8%).

FORM



[Click here to electronically enroll a patient in the Opsumit REMS](#)

Materials for Healthcare Providers

- ↓ [Prescriber and Pharmacy Guide](#)
- ↓ [Prescriber Enrollment and Agreement Form](#)
- ↓ [Patient Enrollment and Consent Form](#)
- ↓ [Patient Enrollment and Consent Form - for VA use only](#)
- ↓ [Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#)

Materials for Pharmacies

- ↓ [Inpatient Pharmacy Enrollment Form](#)
- ↓ [Prescriber and Pharmacy Guide](#)

Materials for Female Patients

- ↓ [Guide for Female Patients](#)

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Prescriber Roles & Responsibilities

Healthcare providers must complete the following steps in the Opsumit REMS:

1. Read the [Opsumit Prescribing Information](#) and the [Prescriber and Pharmacy Guide](#) to understand the risks of Opsumit, and to learn about the Opsumit REMS

- Prescribers must understand the risks of Opsumit, and become familiar with the Opsumit REMS

2. Complete a [Prescriber Enrollment and Agreement Form](#)

- You can download the [Prescriber Enrollment and Agreement Form](#) here and fax it to [Actelion Pathways](#)® at 1-866-279-0669 **or** you may enroll by calling [Actelion Pathways](#) at 1-866-228-3546. [Actelion Pathways](#) administers the Opsumit REMS. After providing your enrollment by phone, you will receive a pre-populated form by fax to sign and fax to 1-866-279-0669
- By signing the form, you will attest to understanding the risks of Opsumit and agree to comply with the Opsumit REMS.

3. Determine the reproductive potential for female patients

- Prescribers should identify female patients (captured on the [Patient Enrollment and Consent Form](#)) as one of the following categories:
 - a. Female of Reproductive Potential
 - Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause (as defined in the [Prescriber and Pharmacy Guide](#))
 - For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal)
 - For the purposes of this REMS, females who have undergone tubal sterilization are classified as females of reproductive potential
 - Or
 - b. Female of Non-Reproductive Potential (choose one of the options below)
 - Pre-pubertal Female of Non-Reproductive Potential
 - Post-menopausal Female of Non-Reproductive Potential
 - Female with other medical reasons for permanent, irreversible infertility

Definitions are provided in the “Opsumit REMS Overview” section of the [Prescriber and Pharmacy Guide](#).

4. Educate and counsel female patients about the risks of Opsumit

- For all females, prescribers must:
 - Advise the patient that Opsumit is only available through a restricted distribution program called the Opsumit REMS
 - Educate and counsel patients about the risks of Opsumit
- For Females of Reproductive Potential, prescribers must:
 - Review with her the [Guide for Female Patients](#)
 - Educate her about
 - the risk of embryo-fetal toxicity;
 - the need to use reliable contraception during Opsumit treatment and for one month following treatment discontinuation; and
 - her need to consider medical options in the event of unprotected sexual intercourse or known or suspected contraception failure.
 - Advise the patient of the requirement for initial and monthly pregnancy tests to confirm they are not pregnant, so they can begin and continue to receive Opsumit
 - Counsel her to immediately contact her healthcare provider if she misses a menstrual period or suspects she is pregnant
 - Counsel her that she must agree to be contacted prior to each shipment to confirm that the pregnancy tests have been completed
- For Females of Non-Reproductive Potential
 - For a Post-menopausal Female or a female with other medical reasons for permanent, irreversible infertility, prescribers must provide the [Guide for Female Patients](#) and instruct her to read it.
 - For Pre-pubertal Females, prescribers must:
 - Review with her and her parent/guardian the [Guide for Female Patients](#)
 - Educate her and her parent/guardian about the risk of serious birth defects
 - Counsel her and her parent/guardian to immediately contact her healthcare provider if she gets her menstrual period
- Prescribers must counsel any patient who fails to comply with the program requirements.

5. Enroll female patients into the Opsumit REMS by completing the [Patient Enrollment and Consent Form](#) via **one** of three options below:

- Enroll a patient [online](#) (see below)
 - Confirm patient has agreed to comply with program requirements and has signed the form where indicated
 - Patients can sign electronically at the time of enrollment by typing their name into the signature box, or signing with their finger or stylus on touchscreen devices. Patients can also provide their email address to provide an electronic signature later.
 - Click the button below and complete the enrollment form
 - Print the form and keep it with the patient's records



- Enroll a patient by [fax](#) using the printed form
 - Download the [Patient Enrollment and Consent Form](#) from this website
 - Confirm patient has agreed to comply with program requirements and has signed the form where indicated
 - Fax the completed form to [Actelion Pathways](#) at 1-866-279-0669. [Actelion Pathways](#) administers the Opsumit REMS
 - Keep the original form with the patient's records
- Enroll a patient by [calling Actelion Pathways](#) at 1-866-228-3546
 - Confirm patient has agreed to comply with program requirements and provided their verbal consent by calling [Actelion Pathways](#) at 1-866-228-3546
 - Sign the pre-populated form faxed by [Actelion Pathways](#) and fax the signed and completed form to [Actelion Pathways](#) at 1-866-279-0669
 - Keep the signed form with the patient's records

Enrollment for VA patients can only be done by faxing a completed and signed [Patient Enrollment and Consent Form - for VA use only](#). Enrollment by phone and online enrollment are not available for VA patients.

6. Check patients' pregnancy status (for Females of Reproductive Potential)

- Order and review pregnancy tests for the patient:
 1. prior to initiating treatment
 2. monthly during treatment
 3. one (1) month after stopping treatment

7. Monitor patients throughout treatment

- For Females of Reproductive Potential, prescribers must:
 - a. Order and review pregnancy tests monthly during treatment with Opsumit and for one month after stopping treatment
 - b. Notify the patient and Actelion if a patient's pregnancy test is positive
 - c. Monitor patients' reproductive status during treatment with Opsumit and report any changes or misclassifications to the Opsumit REMS by completing and submitting a [Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#) **or** contacting [Actelion Pathways](#) at 1-866-228-3546 within 10 business days of becoming aware of the change.
- For Females of Non-Reproductive Potential, prescribers must:
 - a. Monitor patients' reproductive status during treatment with Opsumit and report any changes or misclassifications to the Opsumit REMS by completing and submitting the [Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#) **or** by contacting [Actelion Pathways](#) at 1-866-228-3546 within 10 business days of becoming aware of the change
 - b. For each Pre-pubertal Female who is at least 8 years of age and older, annually verify and report the reproductive status by completing and submitting the [Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#) **or** by contacting [Actelion Pathways](#) at 1-866-228-3546



Reporting to Actelion

To report any pregnancies and suspected adverse reactions, contact Actelion at 1-866-228-3546.

Reporting to FDA MedWatch

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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Information for Female Patients

What is Opsumit (macitentan)?

Opsumit is a prescription medicine used to treat pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs.

Opsumit can improve your ability to exercise, improve some of your symptoms, and help slow down the progression of your disease. Opsumit can also lower your chance of being hospitalized for PAH.

It is not known if Opsumit is safe and effective in children.

What are the serious risks of Opsumit?

Opsumit can cause **serious birth defects** if taken during pregnancy. Women must not be pregnant when they start taking Opsumit or become pregnant while taking Opsumit.

What is the Opsumit REMS (Risk Evaluation and Mitigation Strategy)?

The Opsumit REMS is a program to tell patients and healthcare providers about the risk of serious birth defects when taking Opsumit. This program is required by the Food and Drug Administration (FDA). All females must enroll in the Opsumit REMS to receive Opsumit. REMS stands for **R**isk **E**valuation and **M**itigation **S**trategy.

Females who **cannot** get pregnant

You are considered a female who is **not** able to get pregnant if you:

- Have not yet entered puberty, or
- Do not have a uterus, or
- Have gone through menopause. (Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed,) or
- Are infertile for other medical reasons and this infertility is permanent and cannot be reversed.

To receive Opsumit, you must:

- Enroll in the Opsumit REMS by completing the [Patient Enrollment and Consent Form](#)
 - Your prescriber will help you complete this form
 - You must understand your requirements in the Opsumit REMS and provide your signature:
 - electronically (if enrolling online), **or**
 - on the form itself (if enrolling by paper), **or**
 - by calling *Actelion Pathways*® to provide your verbal consent (if enrolling by phone)
- Tell your prescriber if you become pregnant or your ability to become pregnant changes
- Receive counseling from your prescriber on the risk of serious birth defects (only if you are premenopausal)
- Be monitored every year to see if your ability to become pregnant changes and tell your prescriber if your ability to become pregnant changes (only if you are over the age of 8)

Note: If you are a parent or caregiver of a female child who started taking Opsumit before reaching puberty, you should check your child regularly to see if she is developing signs of puberty. Tell your doctor right away if you notice that she is developing breast buds or pubic hair. Your doctor should decide if your child has reached puberty. Your child may reach puberty before having her first menstrual period

Females who **can** get pregnant

You are considered a female who can get pregnant if you:

- Have entered puberty, even if you have not started your period, and
- Have a uterus, and
- Have not gone through menopause (have not had a period for at least 12 months for natural reasons, or have had your ovaries removed)

To receive Opsumit, you must:

- Enroll in the Opsumit REMS by completing the [Patient Enrollment and Consent Form](#)
 - Your prescriber will help you complete this form
 - You must understand your requirements in the Opsumit REMS and provide your signature:
 - electronically (if enrolling online), **or**
 - on the form itself (if enrolling by paper), **or**
 - by calling *Actelion Pathways* to provide your verbal consent (if enrolling by phone)
- Talk to your healthcare provider about the risks and benefits of Opsumit
- Read the [Guide for Female Patients](#)
- Have a negative pregnancy test:
 - before you start taking Opsumit
 - each month before you receive your refill
 - for one month after you stop taking Opsumit
 Your healthcare provider will order the pregnancy tests for you. You may not receive your Opsumit refill on time if you do not confirm with the pharmacy that you have had your monthly pregnancy test
- Use reliable forms of birth control at all times during Opsumit treatment and for one month after stopping treatment with Opsumit
- Do not have unprotected sex
- Immediately notify your healthcare provider if you miss a menstrual period or suspect you are pregnant

Please see the resources below to learn more about taking Opsumit and the Opsumit REMS.



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Pharmacy Certification

Due to the risk of serious birth defects, Opsumit is only available through a network of certified pharmacies. For information on Opsumit certified pharmacies or wholesale distributors, please call *Actelion Pathways*® at 1-866-228-3546.

Outpatient Pharmacy Certification

Opsumit will be dispensed to outpatients by a limited number of certified pharmacies. Prior to dispensing Opsumit the pharmacy will confirm that the prescriber who wrote the prescription is enrolled, and if the patient is a female that she is enrolled in the Opsumit REMS. If either the female or prescriber is not enrolled, Opsumit will not be dispensed.

For Females of Reproductive Potential, pharmacies will:

- Ask the patient if she has had a pregnancy test within the last month
- Counsel her on the need to use reliable contraception during Opsumit treatment and for one month after stopping treatment
- Counsel her to inform her prescriber immediately if she misses a menstrual period or suspects that she may be pregnant or if her reproductive status changes

For Pre-pubertal Females, pharmacies will:

- Counsel her to inform her healthcare provider immediately if her reproductive status changes

Females of Reproductive Potential and Pre-pubertal Females will only be able to get a 30-day supply of Opsumit at one time. The [Opsumit Medication Guide](#) will be provided to all patients each time Opsumit is dispensed.

Inpatient Pharmacy Certification

This inpatient pharmacy will:

- Dispense only to those patients under the supervision and care of a healthcare provider who is enrolled in the Opsumit REMS
- Dispense to a female patient only after she has been enrolled in the Opsumit REMS or if she will be enrolled prior to discharge from this healthcare facility. A female who has not been enrolled by the certified prescriber will not have access to Opsumit in the outpatient setting until such time that registration has been completed
- Dispense no more than a fifteen (15) day temporary supply of Opsumit upon discharge of any patient
- Not transfer Opsumit to any pharmacy, practitioner, or healthcare setting not certified by *Actelion Pathways*

To be certified in the Opsumit REMS, an authorized representative of the inpatient pharmacy must:

- Read the Opsumit Prescribing Information and [Prescriber and Pharmacy Guide](#).
- Put processes and procedures in place to ensure the Opsumit REMS requirements are met
- Ensure training of dispensing staff on the Opsumit REMS procedures and materials, including the [Prescriber and Pharmacy Guide](#) prior to dispensing Opsumit
- Enroll in the Opsumit REMS if the inpatient pharmacy designates a new authorized representative by completing, signing, and submitting a new [Inpatient Pharmacy Enrollment Form](#) as soon as the designated authorized representative changes.
- Notify Actelion Pharmaceuticals US, Inc. ("Actelion") or FDA if any patient becomes pregnant during Opsumit treatment
- Develop a process to track compliance with the conditions above and provide information about its compliance to Actelion
- Agree that this pharmacy may be subject to an audit by the FDA, Actelion, or a designated third party
- Agree to follow the REMS requirements by completing and submitting an [Inpatient Pharmacy Enrollment Form](#) to the Opsumit REMS
 - Authorized representatives can complete the [Inpatient Pharmacy Enrollment Form](#) by:
 - faxing the printed form to 1-866-279-0669
 - calling the Opsumit REMS at 1-866-228-3546

If an inpatient pharmacy needs Opsumit and is not enrolled in the Opsumit REMS, the inpatient pharmacy can contact *Actelion Pathways* at 1-866-228-3546 for assistance in obtaining a 15-day supply of Opsumit for a specific inpatient while initiating enrollment.



You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

To learn more about the serious risks associated with Opsumit, please refer to the resources below.



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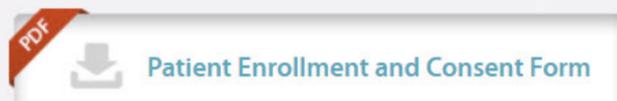
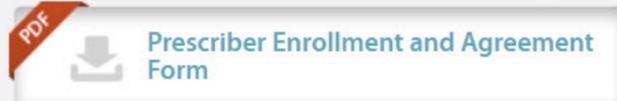
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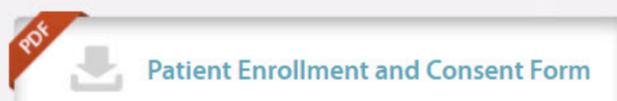
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Patient Enrollment and Consent

Opsumit® is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS).

^ Patient Information

* First name	Middle Initial	* Last name	Gender
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Male <input type="radio"/> Female
* Birth date	Primary language	Email address	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Primary phone #	Alternate phone #	Best time to call	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
* Address	City	State	* Zip
<input type="text"/>	<input type="text"/>	Select One <input type="text"/>	<input type="text"/>
Legal guardian	Relationship	Phone #	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Emergency contact	Relationship	Phone #	
<input type="text"/>	<input type="text"/>	<input type="text"/>	

Continue

^ Female Patient Agreement

^ Prescriber Information

^ Prescriber Authorization

Submit

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Patient Enrollment and Consent

Opsumit® is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS).

^ Patient Information

Patient information has been captured.

Modify

^ Female Patient Agreement

How do you want to provide female patient's agreement?

- Patient or legal guardian is here to sign
- Email patient
- Skip for now

^ Prescriber Information

^ Prescriber Authorization

Submit



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Patient Enrollment and Consent

Opsumit® is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS).

^ Patient Information

Patient information has been captured.

Modify

^ Female Patient Agreement

How do you want to provide female patient's agreement?

- Patient or legal guardian is here to sign
 Email patient
 Skip for now

* Who is signing the agreement?

- Patient
 Legal guardian

* Female Patient Agreement

For All Females: I acknowledge that I understand that Opsumit is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS). I acknowledge that I have received and read the *Guide for Female Patients*.
For Females Who Can Get Pregnant: I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects. I have read the *Guide for Female Patients*. I understand that I will be contacted by Actelion and/or its agents and contractors to receive counseling and education on the Opsumit REMS and the risk of serious birth defects, the need to use reliable contraception during Opsumit treatment and for 1 month after stopping Opsumit treatment, the

I Agree (Required)

* Signer's Full Name

Type It Sign It

Signature Preview

* Witness

I, [User Name] attest to in witness whereof, [Patient Name] signing the patient authorization and release. (Required)

* Initials

Continue

^ Prescriber Information

^ Prescriber Authorization

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Opsumit® is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS).

^ Patient Information

Patient information has been captured.

Modify

^ Female Patient Agreement

Female patient agreement has been captured.

Modify

^ Prescriber Information

* First name

Middle Initial

* Last name

* Address

City

State

Select One ▾

* Zip

Phone #

Opsumit Prescriber ID

Fax #

* NPI #

Office contact and email address

Continue

^ Prescriber Authorization

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^ Patient Information

Patient information has been captured.

Modify

^ Female Patient Agreement

How do you want to provide female patient's agreement?

- Patient or legal guardian is here to sign
- Email patient
- Skip for now

Patients have the ability to submit consent electronically.
If available, please provide the patient's e-mail address below so that we can send them the above link to obtain consent. The patient's e-mail address will not be used for any other purpose.

* Patient's Email:

Send Email

^ Prescriber Information

^ Prescriber Authorization

Submit

From: OPSUMIT REMS <messaging@iassist.com>
Sent: [Weekday], [Month] [Day], [Year] [hh]:[mm] [AM/PM]
To: [Patient Name] <patient_email@domain.tld>
Subject: OPSUMIT® REMS Enrollment Reminder from Dr. [First Name] [Last Name]

Dear [Patient],

During your last appointment with Dr. [First Name] [Last Name] on [Month] [Day], [Year], and after careful review of our records, we did not receive your signature on the OPSUMIT® REMS Patient Enrollment and Consent form. To complete your enrollment in OPSUMIT® REMS and have access to OPSUMIT®, please click [here](#) and complete the online form.

Thank you!

OPSUMIT® REMS

This message is intended solely for the designated recipient(s). It may contain confidential or proprietary information and may be subject to attorney-client privilege or other confidentiality protections. If you are not a designated recipient you may not review, copy or distribute this message. If you receive this in error, please notify the sender by reply e-mail and delete this message. Thank you.

This is an automated message sent from:

OpsumitREMS.com

Date Created (RFC 822): [Weekday], [Day] [Month], [Year] [hh]:[mm]:[ss] +0000

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^ Patient Information

* First name	Middle Initial	* Last name	* Gender
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Male <input type="radio"/> Female
* Birth date	Primary language	Email address	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Primary phone #	Alternate phone #	Best time to call	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Address	City	State	* Zip
<input type="text"/>	<input type="text"/>	Select One <input type="button" value="v"/>	<input type="text"/>
Legal guardian	Relationship	Phone #	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Emergency contact	Relationship	Phone #	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
* Last 4 Digits of SSN			
<input type="text"/>			

Continue

^ Female Patient Agreement

^ Prescriber Information

Submit



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^ Patient Information

Patient information has been captured.

Modify

^ Female Patient Agreement

Who is authorizing?

- Patient
- Legal guardian

^ Prescriber Information

Submit



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^ Patient Information

Patient information has been captured.

Modify

^ Female Patient Agreement

Who is authorizing?

- Patient
 Legal guardian

* Female Patient Agreement

For All Females: I acknowledge that I understand that Opsumit is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS). I acknowledge that I have received and read the *Guide for Female Patients*.

For Females Who Can Get Pregnant: I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects. I have read the *Guide for Female Patients*. I understand that I will be contacted by Actelion and/or its agents and contractors to receive counseling and education on the Opsumit REMS and the risk of serious birth defects, the need to use reliable contraception during Opsumit treatment and for 1 month after stopping Opsumit treatment, the

I Agree (Required)

* Signer's Full Name

Type It Sign It

Signature Preview

Continue

^ Prescriber Information

Submit

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^ Patient Information

Patient information has been captured.

Modify

^ Female Patient Agreement

Who is authorizing?

Patient

Legal guardian

* Relationship to Patient

* Female Patient Agreement

For All Females: I acknowledge that I understand that Opsumit is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS). I acknowledge that I have received and read the *Guide for Female Patients*.

For Females Who Can Get Pregnant: I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects. I have read the *Guide for Female Patients*. I understand that I will be contacted by Actelion and/or its agents and contractors to receive counseling and education on the Opsumit REMS and the risk of serious birth defects, the need to use reliable contraception during Opsumit treatment and for 1 month after stopping Opsumit treatment, the

I Agree (Required)

* Signer's Full Name

Type It

Sign It

Signature Preview

Continue

^ Prescriber Information

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^ Patient Information

Patient information has been captured.

Modify

^ Female Patient Agreement

Female patient agreement has been captured.

Modify

^ Prescriber Information

Prescriber First Name

Prescriber Last Name

Continue

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^ Patient Information

Patient information has been captured.

Modify

^ Female Patient Agreement

Female patient agreement has been captured.

Modify

^ Prescriber Information

Prescriber information has been captured.

Modify

! Preview the Patient Enrollment and Consent form, then click "Submit."

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^ Patient Information

Patient information has been captured.

[Modify](#)

^ Female Patient Agreement

Female patient agreement has been captured.

[Modify](#)

^ Prescriber Information

Prescriber information has been captured.

[Modify](#)

! Preview the Patient Enrollment and Consent form, then click "Submit."

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^ Patient Information

Patient information has been captured.

Modify

^ Female Patient Agreement

An email has been sent to the patient with instructions to provide Female Patient's Agreement.

Modify

^ Prescriber Information

* First name	Middle Initial	* Last name
<input type="text"/>	<input type="text"/>	<input type="text"/>
* Address	City	
<input type="text"/>	<input type="text"/>	
State	* Zip	Phone #
<input type="text" value="Select One"/>	<input type="text"/>	<input type="text"/>
Fax #	* NPI #	Opsumit Prescriber ID
<input type="text"/>	<input type="text"/>	<input type="text"/>
		Office contact and email address
		<input type="text"/>

Continue

^ Prescriber Authorization

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^ Patient Information

Patient information has been captured.

Modify

^ Female Patient Agreement

Female Patient Agreement has been skipped.

Modify

^ Prescriber Information

* First name

Middle Initial

* Last name

* Address

City

State

Select One ▾

* Zip

Phone #

Opsumit Prescriber ID

Fax #

* NPI #

Office contact and email address

Continue

^ Prescriber Authorization

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^ Patient Information

Patient information has been captured.

Modify

^ Female Patient Agreement

Female patient agreement has been skipped.

Modify

^ Prescriber Information

Prescriber information has been captured.

Modify

^ Prescriber Authorization

* Check correct female patient category (please see definitions of these terms below)

Female of Reproductive Potential

If this patient is a Female of Reproductive Potential (which includes females who have undergone tubal sterilization), has a negative pregnancy test been completed prior to prescribing Opsumit?

- Yes
 No

Female of Non-Reproductive Potential

- Pre-pubertal Female
 Post-menopausal Female
 Female with other medical reasons for permanent, irreversible infertility

* Check the box below agreeing to the accuracy of the information.

Prescriber Authorization

For All Females

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) that Opsumit is only available through a restricted distribution program under an FDA-required REMS
- I will evaluate the patient and agree to document any change or misclassification in reproductive potential status by submitting a *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* or contact Actelion Pathways® at 1-866-228-3546 within 10 business days of becoming aware of the change

For Females of Reproductive Potential

- I acknowledge that I have counseled the patient (and parent/guardian when

- I certify that the above therapy ordered is medically necessary and agree to follow the "Prescriber Requirements" above. Further, I hereby authorize Actelion and/or its designated representative(s), to act on my behalf for the limited purposes of providing this prescription to the certified specialty pharmacy for patient treatment purposes. (Required)

Prescriber Signature

* Prescriber's Full Name

Type It Sign It

Signature Preview

Definitions of Reproductive Potential Status

Females of Reproductive Potential

- Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause (as defined below)
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal)
- For the purposes of this REMS, females who have undergone tubal sterilization are classified as females of reproductive potential

Females of Non-Reproductive Potential

- Pre-pubertal Females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential
- Post-menopausal Females: Females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy
- Females with other medical reasons for permanent, irreversible infertility

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^ Patient Information

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Modify

^ Female Patient Agreement

Female patient agreement has been captured.

Modify

^ Prescriber Information

Prescriber information has been captured.

Modify

^ Prescriber Authorization

Prescriber authorization has been captured.

Modify

! Preview the Patient Enrollment and Consent form, then click "Submit."

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^ Patient Information

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Modify

^ Female Patient Agreement

Female patient agreement has been captured.

Modify

^ Prescriber Information

Prescriber information has been captured.

Modify

^ Prescriber Authorization

Prescriber authorization has been captured.

Modify

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Patient Enrollment and Consent



Thank you for your submission

Patient Enrollment and Consent Form

 [Preview](#)
