

[Home](#)

[Prescriber Roles
& Responsibilities](#)

[Information for
Female Patients](#)

[Pharmacy
Certification](#)

[Enrollment Forms
& Other Resources](#)

[Changes to the
Opsumit REMS Program](#)

Opsumit REMS (Risk Evaluation and Mitigation Strategy) Program

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

The goals of the Opsumit REMS are:

- To inform prescribers, patients, and pharmacists about the risk of serious birth defects and safe-use conditions for Opsumit
- To minimize the risk of fetal exposure and adverse fetal outcomes in females of reproductive potential prescribed Opsumit:
 - a. Females who are pregnant must not be prescribed Opsumit
 - b. Females taking Opsumit must not become pregnant

Prescribers

For Prescriber Information

[Click Here](#)

Female Patients

For Patient Information

[Click Here](#)

Opsumit REMS Program Overview:

- All healthcare providers must enroll in the Opsumit REMS Program and comply with requirements to prescribe Opsumit
- All female patients must be enrolled in the Opsumit REMS Program 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 Program and agree to the REMS requirements
- Pharmacies that supply inpatient use of Opsumit must also be certified by enrolling in the Opsumit REMS Program and agreeing to the REMS requirements

Changes to the Opsumit Risk Evaluation and Mitigation Strategy (REMS) Program November 2015

- New definition of Female of Non-Reproductive Potential
- Revised Form: [Opsumit REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#)
- Audits will be performed for a select number of inpatient pharmacies

Opsumit® is an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression. Disease progression included: death, initiation of intravenous (IV) or subcutaneous prostanoids, or clinical worsening of PAH (decreased 6-minute walk distance, worsened PAH symptoms and need for additional PAH treatment). Opsumit also reduced 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 were treated with Opsumit monotherapy or in combination with phosphodiesterase-5 inhibitors or inhaled prostanoids. 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%).

Materials for Healthcare Providers

- ↓ [Prescriber and Pharmacy Guide for the Opsumit REMS Program](#)
- ↓ [Opsumit REMS Prescriber Enrollment and Agreement Form](#)
- ↓ [Opsumit Patient Enrollment and Consent Form](#)
- ↓ [Opsumit REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#)

Materials for Female Patients

- ↓ [Opsumit REMS Guide for Females Who Can Get Pregnant](#)
- ↓ [Opsumit Medication Guide](#)

Prescriber Roles & Responsibilities

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

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

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

2. Complete an [Opsumit REMS Prescriber Enrollment and Agreement Form](#)

- By signing the form, you will attest to understanding the risks of Opsumit and agree to comply with the Opsumit REMS Program. You can download the [Opsumit REMS Prescriber Enrollment and Agreement Form](#) here and fax it to [Actelion Pathways](#)* at 1-866-279-0669. [Actelion Pathways](#) administers the Opsumit REMS Program

3. Determine the reproductive potential for female patients

- Prescribers should identify female patients (captured on the [Opsumit Patient Enrollment and Consent Form](#)) as one of the following categories:
 - Female of Reproductive Potential
Or
 - 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 Program Overview" section of the [Prescriber and Pharmacy Guide for the Opsumit REMS Program](#).

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 Program
 - Educate and counsel patients about the risks of Opsumit
- For Females of Reproductive Potential, prescribers must:
 - Review with her the [Opsumit Medication Guide](#) and the [Opsumit REMS Guide for Females Who Can Get Pregnant](#)
 - Educate her about
 - the risk of teratogenicity;
 - 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 [Opsumit Medication Guide](#) and instruct her to read it
 - For Pre-pubertal Females, prescribers must:
 - Review with her and her parent/guardian the [Opsumit Medication Guide](#)
 - 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 Program by completing the [Opsumit Patient Enrollment and Consent Form](#)

- 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 Program
- Keep the original form with patient's records

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:
 - 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 Program by completing and submitting an [Opsumit REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#) within 10 business days of becoming aware of the change.
- For Females of Non-Reproductive Potential, prescribers must:
 - Monitor patients' reproductive status during treatment with Opsumit and report any changes or misclassifications to the Opsumit REMS Program by completing and submitting the [Opsumit REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#) 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 [Opsumit REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#)



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.

[Home](#)

[Prescriber Roles & Responsibilities](#)

[Information for Female Patients](#)

[Pharmacy Certification](#)

[Enrollment Forms & Other Resources](#)

[Changes to the Opsumit REMS Program](#)

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) Program?

The Opsumit REMS Program 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 Program to receive Opsumit. REMS stands for **R**isk **E**valuation and **M**itigation **S**trategy.

If you are a female who can get pregnant, to receive Opsumit you must:

- Talk to your healthcare provider about the risks and benefits of Opsumit
- Read:
 - a. The [Opsumit Medication Guide](#) and
 - b. The [Opsumit REMS Guide for Females Who Can Get Pregnant](#)
- Have a pregnancy test before you start taking Opsumit
- Have a pregnancy test before you receive your refill each month
- Use reliable forms of birth control during Opsumit treatment and for one month after stopping treatment with Opsumit
- 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 Program.



- Home
- Prescriber Roles & Responsibilities
- Information for Female Patients
- Pharmacy Certification
- Enrollment Forms & Other Resources
- Changes to the Opsumit REMS Program

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 Program. 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 Program
- Dispense to a female patient only after she has been enrolled in the Opsumit REMS Program 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 Program, an authorized representative of the inpatient pharmacy must:

- Read the Opsumit Prescribing Information, [Opsumit Medication Guide](#) and [Prescriber and Pharmacy Guide for the Opsumit REMS Program](#)
- Put processes and procedures in place to ensure the Opsumit REMS Program requirements are met
- Ensure training of dispensing staff on the Opsumit REMS program procedures and materials, including the [Prescriber and Pharmacy Guide for the Opsumit REMS Program](#) prior to dispensing Opsumit
- 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 [Opsumit REMS Inpatient Pharmacy Enrollment Form](#) to the Opsumit REMS Program
 - Authorized representatives can complete the [Opsumit REMS Inpatient Pharmacy Enrollment Form](#):
 - By fax at 1-866-279-0669
 - By calling the Opsumit REMS Program at 1-866-228-3546

If an inpatient pharmacy needs Opsumit and is not enrolled in the Opsumit REMS Program, 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.



- Home
- Prescriber Roles & Responsibilities
- Information for Female Patients
- Pharmacy Certification
- Enrollment Forms & Other Resources
- Changes to the Opsumit REMS Program

Enrollment Forms & Other Resources

Materials for Healthcare Providers

-   [Opsumit REMS Prescriber Enrollment and Agreement Form](#)
-   [Prescriber and Pharmacy Guide for the Opsumit REMS Program](#)
-   [Opsumit Patient Enrollment and Consent Form](#)
-   [Opsumit REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#)

Materials for Female Patients

-   [Opsumit REMS Guide for Females Who Can Get Pregnant](#)
-   [Opsumit Medication Guide](#)
-   [Opsumit Patient Enrollment and Consent Form](#)

Materials for Pharmacies

-   [Opsumit REMS Inpatient Pharmacy Enrollment Form](#)