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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<sup>®</sup> 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](#)

## 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

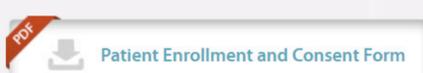
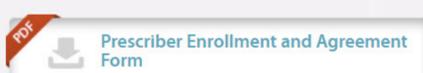
Enrollment for VA patients can only be done by faxing a completed and signed [Patient Enrollment and Consent Form - for VA use only](#). Enrollment by phone and online enrollment are not available for VA patients.

**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](http://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](http://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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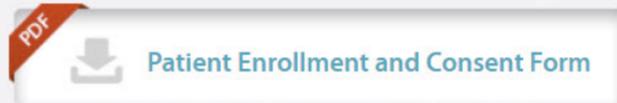
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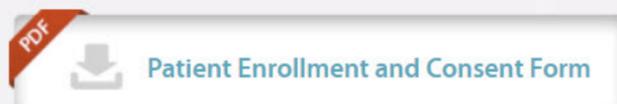
### Materials for Healthcare Providers



### Materials for Pharmacies



### Materials for Female Patients



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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**

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

Continue

**^ Female Patient Agreement**

**^ Prescriber Information**

**^ Prescriber Authorization**

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## Patient Enrollment and Consent

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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

### ^ Prescriber Information

### ^ Prescriber Authorization

Submit



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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

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Modify

### ^ Female Patient Agreement

Female patient agreement has been captured.

Modify

### ^ Prescriber Information

\* First name

Middle Initial

\* Last name

\* Address

City

State

\* Zip

Phone #

Opsumit Prescriber ID

Fax #

\* NPI #

Office contact and email address

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### ^ 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](mailto:messaging@iassist.com)>  
**Sent:** [Weekday], [Month] [Day], [Year] [hh]:[mm] [AM/PM]  
**To:** [Patient Name] <[patient\\_email@domain.tld](mailto: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.

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This is an automated message sent from:

[OpsumitREMS.com](http://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="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"/>	
* Last 4 Digits of SSN			
<input type="text"/>			

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^ Female Patient Agreement

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### ^ Patient Information

Patient information has been captured.

Modify

### ^ Female Patient Agreement

Who is authorizing?

- Patient
- Legal guardian

### v Prescriber Information

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- Patient  
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\* 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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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

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

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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

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](#)

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## Patient Enrollment and Consent

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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](#)

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## Patient Enrollment and Consent

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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 #
Select One ▾	<input type="text"/>	<input type="text"/>
Opsumit Prescriber ID		
<input type="text"/>		
Fax #	* NPI #	Office contact and email address
<input type="text"/>	<input type="text"/>	<input type="text"/>

Continue

### ^ Prescriber Authorization

Submit



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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 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

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

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

Patient information has been captured.

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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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

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**

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Patient Enrollment and Consent Form

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