

# Opsumit<sup>®</sup> REMS (Risk Evaluation and Mitigation Strategy) Guide for Female Patients

Information to help you throughout your treatment with Opsumit



Opsumit.  
macitentan tablets 10 mg

ACTELION  
Pathways<sup>®</sup>

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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.

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## 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
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## 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 <b>PLUS One method from this list:</b> Male condom		Partner's vasectomy <b>PLUS One method from this list:</b> 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



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**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](http://www.OpsumitREMS.com).**

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

