Opsumit® REMS Prescriber Enrollment and Agreement Form

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

You can also reach *Actelion Pathways* via phone at 1-866-ACTELION (1-866-228-3546)

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Prescriber Information (please print)

First name | MI | Last name

☐ MD ☐ DO ☐ PA ☐ NP

Email address | NPI # | Professional designation

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 | ☐ Phone ☐ Fax ☐ Email Preferred method of contact

Secondary

Office practice/Clinic name | Affiliated hospital

Specialty | Office contact name | Office contact phone

Office email address | Phone | Fax

Address | City

State | ZIP | ☐ Phone ☐ Fax ☐ Email Preferred method of contact

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) Program, monitor them appropriately, and report any pregnancies to the Opsumit REMS Program.

Specifically, you attest to the following:

- I have read the Opsumit Prescribing Information, the *Opsumit Medication Guide*, and the *Prescriber and Pharmacy Guide for the Opsumit REMS Program* and agree to comply with the Opsumit REMS Program requirements
- I agree to enroll all female patients into the Opsumit REMS Program
- I will:
  - Determine the reproductive potential status of all female patients using the definitions provided in the *Prescriber and Pharmacy Guide for the Opsumit REMS Program*
  - Advise all females that Opsumit is only available through a restricted distribution program called the Opsumit REMS Program
  - Counsel Females of Reproductive Potential (FRP) on the risks of Opsumit, including the risk of serious birth defects, and review the *Opsumit Medication Guide* and the *Opsumit REMS Program Guide for Females Who Can Get Pregnant* 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 *Opsumit Medication Guide* 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
  - Verify the reproductive potential status annually for Pre-pubertal Females who are at least 8 years of age and older by submitting an *Opsumit REMS 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 one month after stopping treatment
  - Counsel FRPs to use reliable contraception during Opsumit treatment, and for one 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 an *Opsumit REMS 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 Program 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 Program.

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