

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.



PO2201512

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.

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