

Opsumit® REMS Inpatient Pharmacy Enrollment 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* at 1-866-ACTELION (1-866-228-3546) for questions.



H02201512

Due to the risk of embryo-fetal toxicity for female patients, Opsumit is available only through a restricted program called the Opsumit REMS (Risk Evaluation and Mitigation Strategy). In order for inpatients to receive Opsumit, females, as well as inpatient pharmacies that wish to stock this product, must enroll in the Opsumit REMS and agree to comply with the requirements of the program. An Authorized Representative must complete and submit this form on behalf of the inpatient pharmacy, or call *Actelion Pathways* at 1-866-228-3546 to enroll.

Inpatient pharmacy information (please print)

Name

Hospital Nursing home Hospice Asylum/Mental facility Assisted Living Prison Rehabilitation
 Other (please specify): _____

Identification (please complete one of the following):

Health Industry Number (HIN #) _____ National Provider Identifier (NPI #) _____
 Other identifier: _____

Address

City _____ State _____ ZIP _____

Phone # _____ Fax # _____

Ship to address (if different from above)

Address

City _____ State _____ ZIP _____

Phone # _____ Fax # _____

Authorized Representative information (please print)

Title:

Hospital pharmacist Head of Pharmacy and Therapeutics (P&T) committee
 Other title: _____

Name

Authorized Representative phone #

Fax #

Authorized Representative email

Authorized Representative consent

This inpatient pharmacy will:

- Put processes and procedures in place to ensure the Opsumit REMS requirements are met
- 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
- Notify Actelion Pharmaceuticals US, Inc. ("Actelion") or FDA if any patient becomes pregnant during Opsumit treatment
- Not transfer Opsumit to any pharmacy, practitioner, or any healthcare setting not certified by *Actelion Pathways*
- Develop a process to track compliance with the conditions above and provide information about its compliance to Actelion
- Re-enroll in the Opsumit REMS if the pharmacy designates a new authorized representative

I attest that I have read the Opsumit Prescribing Information and *Prescriber and Pharmacy Guide* available at www.OpsumitREMS.com.

I will ensure training of dispensing staff on the Opsumit REMS procedures and materials, including the *Prescriber and Pharmacy Guide* prior to dispensing Opsumit.

I agree that this pharmacy may be audited by the FDA, Actelion, or a designated third-party.

Note: If your inpatient pharmacy needs Opsumit and is not enrolled in the Opsumit REMS, 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.

Signature

Date

Please visit www.OpsumitREMS.com or call 1-866-ACTELION (1-866-228-3546) for more information about the Opsumit REMS.

© 2019 Actelion Pharmaceuticals US, Inc. All rights reserved. MRC-2019-REMS-0009

Reference ID: 4586229