Opsumit® REMS Patient Enrollment and Consent Form

Complete this form for ALL patients.
Fax this completed form to 1-866-279-0669.
Contact *Actelion Pathways*® at 1-866-228-3546 for questions.

EO2201512

1 Patient Information (please print)

First name | Middle initial | Last name | ☐ Male ☐ Female Gender

Birth date | Primary language | Email address

Primary phone # | Alternate phone # | Best time to call

Address | City | State | ZIP

Legal guardian | Relationship | Phone #

Emergency contact | Relationship | Phone #

2 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).

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 *Opsumit Medication Guide* and the *Opsumit REMS Guide for Females Who Can Get Pregnant*. I understand that I will be contacted by Actelion and/or its agents and contractors to receive counseling and education on the Opsumit REMS Program and the risk of serious birth defects, the need to use reliable contraception during Opsumit treatment and for one month after stopping Opsumit treatment, the importance of not becoming pregnant, and to ensure that I have completed pregnancy testing: before I start Opsumit, monthly before each refill, and for one month after stopping Opsumit. I agree to be counseled each month by the certified pharmacy on the need to use reliable contraception during Opsumit treatment and for one month after stopping Opsumit. I understand that I must immediately contact my healthcare provider if I miss a menstrual period or suspect that I am pregnant; and that I may be contacted by Actelion and/or its agents and contractors to obtain information about my pregnancy, if I become pregnant.

For Pre-pubertal Females: I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects, and that I have read the *Opsumit Medication Guide*. I understand that I must immediately contact my healthcare provider if I get my menstrual period.

For Post-menopausal Females: I acknowledge that I have received and read the *Opsumit Medication Guide*.

For Females with other medical reasons for permanent, irreversible infertility: I acknowledge that I have received and read the *Opsumit Medication Guide*.

★ (REQUIRED FOR ALL FEMALES) Patient or Parent/Guardian Signature | Date

3 Prescriber Information (please print)

First name | Middle initial | Last name

Address | City

State | ZIP | Phone # | Opsumit Prescriber ID

Fax # | NPI # | Office contact and email address

4 Prescriber Authorization: If your patient is FEMALE, check correct female patient category (please see definitions of these terms on the following page):

REQUIRED (Check one box)

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**

I certify that the above therapy ordered is medically necessary and agree to follow the "Prescriber Requirements" indicated on the second page of this form. 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 FOR ALL PRESCRIBERS) Prescriber Signature | Date

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

Prescriber Requirements

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 an *Opsumit REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* 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 appropriate) on the risks of Opsumit, including the risk of serious birth defects, and that I have reviewed the *Opsumit Medication Guide* and the *Opsumit REMS Guide for Females Who Can Get Pregnant* with the patient (and parent/guardian when appropriate)
- I will order and review pregnancy tests prior to initiation of Opsumit treatment, monthly during treatment, and for 1 month after stopping treatment in accordance with the Opsumit REMS Program

For Pre-pubertal Females

- I acknowledge that I have counseled the patient and parent/guardian on the risks of Opsumit, including the risk of serious birth defects, and that I have reviewed the *Opsumit Medication Guide* with the patient and parent/guardian
- I will evaluate the patient's reproductive potential status, verify reproductive potential status annually for Pre-pubertal Females who are at least 8 years of age and older, and agree to report any change or misclassification in reproductive potential status on an *Opsumit REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* within 10 business days of becoming aware of the change

5 Fax this form to 1-866-279-0669

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