

# Opsumit® REMS Patient Enrollment and Consent Form

Complete this form for ALL patients.

For immediate patient enrollment, please go to [OpsumitREMS.com](http://OpsumitREMS.com), or call Opsumit REMS at 1-866-228-3546, or fax this completed form to 1-866-279-0669.

Contact Opsumit REMS at 1-866-228-3546 for questions.



\*EO2201512\*

## 1 Patient Information (please print)

First name			Middle initial	Last name		<input type="checkbox"/> Male <input type="checkbox"/> Female	
Birth date		Primary language		Email address			Gender
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). I acknowledge that I have received and read the *Guide for Female Patients*.

**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 *Guide for Female Patients*. I understand that I will be contacted by Janssen and/or its agents and contractors to receive counseling and education on the Opsumit REMS and the risk of serious birth defects, the need to use reliable contraception during Opsumit treatment and for 1 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 1 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 1 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 Janssen 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. 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 been counseled on the risks of Opsumit, including the risk of serious birth defects.

**For Females with other medical reasons for permanent, irreversible infertility:** I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects.

★ \_\_\_\_\_  
(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 category)

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 Opsumit 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.

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(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 a *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* or contacting Opsumit REMS at 1-866-228-3546 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 *Guide for Female Patients* 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

### 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 *Guide for Female Patients* 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 a *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* or contact Opsumit REMS at 1-866-228-3546 within 10 business days of becoming aware of the change

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

Please visit [www.OpsumitREMS.com](http://www.OpsumitREMS.com) or call 1-866-228-3546 for immediate patient enrollment, or for more information about the Opsumit REMS.