

Complete and submit online at www.FILSPARIREMS.com or complete and fax this form to 1-833-483-4736.

Complete this form **only** to change the reproductive status of a patient.

Prescribers must complete this form within 10 business days of awareness of the change in reproductive potential status.

1. Patient Information (*indicates required field)

*First Name:	Middle Initial:	*Last Name:
*Address Line #1:		
Address Line #2:		
*City:	*State:	*Zip:
*Birthdate (MM-DD-YYYY):	Phone:	

2. Prescriber Information (*indicates required field)

*First Name:	*Last Name:
*National Provider Identifier (NPI) #:	Email:
Phone:	Fax:

Definitions of Reproductive Potential Status

Patients Who Can Become Pregnant

- Patients with a uterus who have entered puberty and all patients with a uterus that have not passed through Menopause (as defined to the right).
- For the purposes of the FILSPARI REMS, puberty includes those patients with a uterus who are at least Tanner Stage 3 and have not yet had a menses (premenarchal).
- For the purposes of the FILSPARI REMS, patients who have undergone tubal sterilization are classified as patients who can become pregnant.

Patients Who Cannot Become Pregnant

- Patients with a uterus who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential.
- Patients with a uterus who have passed through Menopause (as defined below).
- Other medical reasons for permanent, irreversible infertility.
- Patients without a uterus (including patients who were born male).

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.

3. Report Change in Status (*indicates required field)

***Based on definitions of reproductive potential status, the patient's status is changing (check one):**

☐ **From a Patient Who Can Become Pregnant to a Patient Who Cannot Become Pregnant**

*If selected, provide reason for change in classification (check one):

- ☐ Physiological transition
 ☐ Medical/surgical (please specify): _____
- ☐ Previous misclassification
 ☐ Other (please specify): _____

☐ **From a Patient Who Cannot Become Pregnant to a Patient Who Can Become Pregnant**

*If selected, provide reason for change in classification (check one):

- ☐ Change from pre-pubertal to patient who can become pregnant
 ☐ Previous misclassification
- ☐ Other (please specify): _____

4. Prescriber Acknowledgement (*indicates required field)

By signing, I certify that the patient's reproductive potential status and reason for submitting this form are accurately noted above. I certify that I will follow the REMS requirements while treating this patient.



*Prescriber Signature:

*Signature Date (MM-DD-YYYY):

Healthcare providers should report adverse events suggestive of hepatotoxicity and pregnancies to the FILSPARI REMS at 1-833-513-1325. Report all other suspected adverse events or product quality complaints associated with FILSPARI to Travele Therapeutics, Inc. at 1-877-659-5518 or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.