

**Instructions:**

1. Review the **Patient Guide**.
2. Enroll by completing the **Patient Enrollment Form** with your healthcare provider and submit to the REMS by fax to 1-833-483-4736.
  - Patient enrollment can also be completed with your healthcare provider online at [www.FILSPARIREMS.com](http://www.FILSPARIREMS.com)

**Complete all required fields on this form to avoid a delay in the enrollment process.**

**1 Patient Information (\*indicates required field)**

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

**2 Patient Agreement**

By completing, signing, and submitting this form, I agree and acknowledge that:

**Before treatment initiation (first dose), I must:**

- Review the **Patient Guide**.
- Get a liver test.
- Receive counseling from my prescriber on the following using the **Patient Guide**:
  - Risk of liver problems
  - Signs and symptoms of liver problems
  - Need to contact the prescriber if I have any signs or symptoms of liver problems
  - Need to complete liver testing every 3 months during treatment.
- Enroll in the REMS by completing the **Patient Enrollment Form** with my prescriber. Enrollment information will be provided to the REMS.

- Receive counseling from the pharmacy on the risk of liver problems associated with FILSPARI treatment.

**During treatment, every 3 months, I must:**

- Get a liver test.
- Adhere to the safe use condition: Communicate with the pharmacy to confirm completion of liver testing.
- Receive counseling from the pharmacy on the risk of liver problems associated with FILSPARI treatment.

**At all times, I must:**

- Inform my prescriber if I have any signs or symptoms of liver problems as described in the **Patient Guide**.

**Provide Signature Below**

By signing below, I acknowledge the above agreements and I understand my personally identifiable information provided above will be shared with Trave Therapeutics, Inc., its agents or contractors and be stored in a secure and confidential database for the FILSPARI REMS. I understand that I may be contacted by Trave Therapeutics, Inc., and its agents about the FILSPARI REMS for voluntary participation in a research study to evaluate possible liver problems while I am receiving FILSPARI. Participation in the study is not required to be enrolled in the REMS or to receive FILSPARI.

\*Patient Signature:

\*Date (MM/DD/YYYY):

\*Parent/Legal Guardian Signature:

\*Date (MM/DD/YYYY):

Parent/Legal Guardian Name (if signing on behalf of patient):

Parent/Legal Guardian Email:

**3 Prescriber Information (\*indicates required field)**

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

**4 Prescriber Authorization (\*indicates required field)**

**\*For this patient, have you reviewed the results of their current liver testing?**

- ☐ Yes (if yes, proceed with signing below)
- ☐ No (if no, necessary testing must be completed before enrolling patient)

**Note: Liver testing is required for all patients. Please complete necessary testing before submitting this form.**

**Provide Signature Below**

By signing below, I acknowledge the patient was provided a copy of the **Patient Guide** and was counseled on the following:

- Risk of hepatotoxicity associated with FILSPARI.
- Signs and symptoms of liver problems, and to contact their prescriber if they experience any signs or symptoms of liver problems.
- The REMS requirements including the need to complete liver testing every 3 months during treatment.
- FILSPARI is only available through a restricted distribution program using the **Patient Guide**.

I will continue to fulfill my obligations under the REMS to include assessing the patient's liver function prior to initiation, then every 3 months during treatment.

\*Prescriber Signature:

\*Date (MM/DD/YYYY):

**Report adverse events suggestive of hepatotoxicity to the FILSPARI REMS at 1-833-513-1325. Report all other suspected adverse events or product quality complaints associated with FILSPARI to Trave Therapeutics, Inc. at 1-877-659-5518 or the FDA at 1-800-FDA-1088 or online at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**