FILSPARI® REMS OUTPATIENT PHARMACY ENROLLMENT FORM

To enroll in the FILSPARI REMS, complete and fax this form to 1-833-483-4736.

Due to the risks of hepatotoxicity and embryo-fetal toxicity, FILSPARI is available only through a restricted program called the FILSPARI REMS (Risk Evaluation and Mitigation Strategy). All outpatient pharmacies that wish to stock FILSPARI must contract with Travere Therapeutics, Inc.

An authorized representative must be designated to carry out the certification process and oversee implementation and compliance with the FILSPARI REMS on behalf of the pharmacy. As the authorized representative, complete and submit this form on behalf of your outpatient pharmacy.

If you have any questions, require additional information, or need further copies of FILSPARI REMS materials, please visit the REMS Website at www.FILSPARIREMS.com, or call the FILSPARI REMS at 1-833-513-1325.

1. Outpatient Pharmacy Information *(*indicates required field)*

*Outpatient Pharmacy Name:			
*Facility National Provider Identifier (NPI) #:	Drug Enforcement Administration Number (DEA #):		
*Pharmacy Address Line #1:			
Pharmacy Address Line #2:			
*City:		*State:	*Zip:
*Phone:	*Fax:		
Pharmacy Ship To Contact			
*First Name:	*Last Name:		
Pharmacy Shipping Address, if different from above			
*Address Line #1:			
Address Line #2:			
*City:		*State:	*Zip:
*Phone:	*Fax:		

2. Outpatient Pharmacy Authorized Representative Information *(*indicates required field)*

*First Name:	*Last Name:
Position/Title: ☐ Pharmacist ☐ Head of Pharmacy and Therapeutics (P&T) committee ☐ Other (please specify):_____	
*Credentials: ☐ RPh ☐ PharmD ☐ Other	
*Authorized Representative Phone:	*Fax:
*Authorized Representative Email:	*Contact Preference (please select one): ☐ Email ☐ Fax

3. Outpatient Pharmacy Authorized Representative Agreement

To become certified to dispense FILSPARI, my pharmacy must:

- Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.
- Have the authorized representative review the ***Prescriber and Pharmacy Guide***.
- Have the authorized representative certify by enrolling in the REMS by completing the ***Outpatient Pharmacy Enrollment Form*** and submitting it to the REMS.
- Train all relevant staff involved in dispensing on the REMS requirements using the ***Prescriber and Pharmacy Guide***.
- Establish processes and procedures to verify the patient is enrolled and the prescriber is certified.
- Establish processes and procedures to document and submit confirmation of counseling on the risks of hepatotoxicity and embryo-fetal toxicity.
- Establish processes and procedures to verify and document the patient's liver testing is complete or the prescriber authorizes the refill, and the reproductive status has not changed.
- For patients who can become pregnant: Establish processes and procedures to verify and document pregnancy testing is complete or the prescriber authorizes the refill.

Before dispensing FILSPARI, my pharmacy must:

- Verify the patient is enrolled and the prescriber is certified through the processes and procedures established as a requirement of the REMS.
- Counsel the patient on the risk of hepatotoxicity. Document and submit confirmation of counseling through the processes and procedures established as a requirement of the REMS.
- For patients who can become pregnant: Counsel the patient on the risk of embryo-fetal toxicity. Document and submit confirmation of counseling through the processes and procedures established as a requirement of the REMS.
- Verify and document the patient's liver testing is complete or the prescriber authorizes the refill, and the reproductive status has not changed through the processes and procedures established as a requirement of the REMS.
- For patients who can become pregnant: Verify and document pregnancy testing is complete or the prescriber authorizes the refill through the processes and procedures established as a requirement of the REMS.

At all times, I must:

- Dispense no more than a 30-days' supply.
- Report pregnancies to the REMS.
- Report adverse events suggestive of hepatotoxicity to the REMS.
- Not distribute, transfer, loan, or sell FILSPARI.
- Maintain and submit records of product dispensing to the REMS.
- Maintain records that all processes and procedures are in place and are being followed.
- Comply with audits carried out by Travere Therapeutics, Inc. or a third party acting on behalf of Travere Therapeutics, Inc. to ensure that all processes and procedures are in place and are being followed.
- Have a new authorized representative enroll by completing and submitting an ***Outpatient Pharmacy Enrollment Form***, if the authorized representative changes.

4. Outpatient Pharmacy Authorized Representative Consent *(*indicates required field)*

By signing below, you agree that you have read the above responsibilities and understand your requirements as an outpatient pharmacy authorized representative, the risks of FILSPARI treatment, and you agree to oversee the implementation of and compliance with the REMS requirements for this pharmacy.

*Authorized Representative 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 Travere Therapeutics, Inc. at 1-877-659-5518 or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.