## FILSPARI® REMS

# INPATIENT PHARMACY ENROLLMENT FORM

#### **Instructions:**

- 1. Review the Prescriber and Pharmacy Guide.
- 2. Enroll by completing and submitting this **Inpatient Pharmacy Enrollment Form** to the REMS by fax to 1-833-483-4736.
  - Inpatient pharmacy enrollment can also be completed online at www.FILSPARIREMS.com

Due to the risk of hepatotoxicity, FILSPARI is available only through a restricted program called the FILSPARI REMS (Risk Evaluation and Mitigation Strategy). All inpatient pharmacies that wish to stock FILSPARI must certify by enrolling in the FILSPARI REMS.

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

1. Inpatient Pharmacy Information (*indicates required field)				
*Inpatient Pharmacy Name:				
*Inpatient Pharmacy Location:   Hospital   Nursing Home  Hospice  Mental Health Facility				
□ Assisted Living □ Prison □ Rehabilitation Facility □ Other (please specify):				
*Facility National Provider Identifier (NPI) #:	Drug Enforcement Administration Number (DEA #):			
Inpatient Pharmacy Address				
*Address Line #1:				
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:	1		
2. Inpatient Pharmacy Authorized Representative Information (*indicates required field)				
* First Name:	Position/Title:			
* Last Name:	<ul><li>☐ Hospital pharmacist</li><li>☐ Head of Pharmacy and Therapeutics (P&amp;T) committee</li></ul>			
	☐ Other (please specify):			
*Authorized Representative Office Phone:	*Fax:			
*Authorized Representative Email:	*Contact Preference (select one): ☐ Email ☐ Fax			

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## 3. Inpatient Pharmacy Authorized Representative Agreement

## As the pharmacy authorized representative, to become certified to dispense FILSPARI, I must:

- Carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.
- Review the Prescriber and Pharmacy Guide.
- Certify by enrolling in the REMS by completing the Inpatient 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 and document the patient is enrolled or will be enrolled prior to discharge, the patient is under the care of a certified prescriber, and liver testing is complete.

## Before dispensing FILSPARI, my pharmacy must:

- 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.
- Verify and document the patient is enrolled or will be enrolled prior to discharge, the patient is under the care of a certified prescriber, and liver testing is complete.

## At discharge, my pharmacy must:

• Dispense no more than a 30-days' supply.

#### At all times, my pharmacy must:

- Report adverse events suggestive of hepatotoxicity to the REMS.
- Not distribute, transfer, loan, or sell FILSPARI, except to certified dispensers.
- 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.

### To maintain certification to dispense, my pharmacy must:

• Have a new authorized representative enroll by completing and submitting an **Inpatient Pharmacy Enrollment Form**, if the authorized representative changes.

## Provide Signature Below

By signing below, I acknowledge the above agreements and my obligations as a FILSPARI inpatient pharmacy authorized representative and agree to oversee the implementation of and compliance with the REMS requirements for this pharmacy. I understand my personally identifiable information provided above will be shared with Travere Therapeutics, Inc., its agents or contractors and entered into a database for the FILSPARI REMS. I agree that I may be contacted in the future by mail, email, fax, and/or phone concerning FILSPARI, the FILSPARI REMS, and other FILSPARI programs and services.

*Authorized Representative Signature:	*Date (MM/DD/YYYY):

Healthcare providers should 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 Travere Therapeutics, Inc. at 1-877-659-5518 or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

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.

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