CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216403Orig1s000

REMS

RISK EVALUATION AND MITIGATION STRATEGY (REMS) DOCUMENT
FILSPARI™ (SPARSENTAN) REMS

I. ADMINISTRATIVE INFORMATION

Risks: hepatotoxicity, embryo-fetal toxicity

Application Number: NDA 216403

Application Holder: Travere Therapeutics, Inc.

Initial REMS Approval: 02/2023

II. REMS GOAL

The goal of the FILSPARI REMS is to mitigate the risks of hepatotoxicity and embryo-fetal toxicity associated with FILSPARI:

- Objective 1: Monitor for elevations in liver enzymes in patients exposed to FILSPARI
- Objective 2: Ensure that patients who can become pregnant are not pregnant before initiating FILSPARI
- Objective 3: Minimize exposure in patients who may become pregnant while taking FILSPARI

III. REMS REQUIREMENTS

Travere Therapeutics, Inc. must ensure that healthcare providers, patients, pharmacies, and wholesalers-distributors comply with the following requirements:

1. Healthcare Providers who prescribe FILSPARI must:

To become certified to prescribe	1. Review the drug's Prescribing Information. 2. Review the following: Prescriber and Pharmacy Guide. 3. Enroll in the REMS by completing the Prescriber Enrollment Form and submitting it to the REMS.

Before treatment initiation (first dose)	4. Counsel the patient on the risk of hepatotoxicity associated with FILSPARI, the signs and symptoms of liver problems, to contact the prescriber if the patient has any signs or symptoms of liver problems, on the REMS requirements including the need to complete liver testing monthly for the first 12 months, then every 3 months during treatment, and that FILSPARI is only available through a restricted distribution program using the Patient Guide. 5. Assess the patient's liver function. Document and submit to the REMS using the Patient Enrollment Form. 6. Assess the patient's reproductive status using the definitions in the Prescriber and Pharmacy Guide. Document and submit to the REMS using the Patient Enrollment Form. 7. For patients who can become pregnant: Counsel the patient about the risk of embryo-fetal toxicity, the need to use effective contraception during treatment and for one month following treatment discontinuation, the need to complete monthly pregnancy tests, the potential need for emergency contraception, and to immediately contact their prescriber if the patient misses a menstrual period or if pregnancy is suspected using the Patient Guide. 8. For patients who can become pregnant: Assess the patient's pregnancy status by ordering a pregnancy test and reviewing the result. Document and submit to the REMS using the Patient Enrollment Form. 9. Provide the patient with the Patient Guide. 10. Enroll the patient by completing the Patient Enrollment Form and submitting it to the REMS.
During treatment; monthly for the first 12 months, then every 3 months	11. Assess the patient's liver function. 12. Counsel the patient on the risk of hepatotoxicity and if they are not complying with the required liver testing.
During treatment; monthly	13. For patients who can become pregnant: Assess the patient's pregnancy status by ordering a pregnancy test and reviewing the result. 14. For patients who can become pregnant: Counsel the patient on the risk of embryo-fetal toxicity, to immediately contact their prescriber if they miss a menstrual period or if pregnancy is suspected, and counsel the patient if they are not complying with the required monthly pregnancy testing or if they are not using effective contraception.
After treatment discontinuation; one month	15. For patients who can become pregnant: Assess the patient's pregnancy status by ordering a pregnancy test and reviewing the result.

At all times	16. Report adverse events suggestive of hepatotoxicity to the REMS. 17. Report pregnancies to the REMS. 18. Assess the patient's reproductive status.
At all times, within 10 business days	19. Report a change or misclassification in reproductive status to the REMS using the Change in Reproductive Potential Status Form.
2. Patients who can become pregnant who are prescribed FILSPARI:	
Before treatment initiation	1. Review the Patient Guide. 2. Get a liver test and a pregnancy test. 3. Receive counseling from the prescriber on the risk of liver problems, the signs and symptoms of liver problems, the need to contact the prescriber if you have any signs or symptoms of liver problems, and the need to complete liver testing monthly for the first 12 months, then every 3 months during treatment using the Patient Guide. 4. Receive counseling from the prescriber on the risk of serious birth defects, the need to use effective contraception during treatment and for one month following treatment discontinuation, the need to complete monthly pregnancy tests, the potential need for emergency contraception, and to immediately contact the prescriber if you miss a menstrual period or suspect that you are pregnant using the Patient Guide. 5. Enroll in the REMS by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS.
During treatment; monthly for the first 12 months, then every 3 months	6. Get a liver test. 7. Adhere to the safe use condition: Communicate with the pharmacy to confirm completion of liver testing.
During treatment; monthly	8. Get a pregnancy test. 9. Receive counseling from the pharmacy on the risks of liver problems and serious birth defects associated with FILSPARI treatment. 10. Adhere to the safe use condition: Communicate with the pharmacy to confirm completion of pregnancy testing.
During treatment and after treatment discontinuation for one month	11. Adhere to the safe use condition: Use effective contraception as described in the Patient Guide.

After treatment discontinuation; one month	12. Get a pregnancy test.
At all times	13. Inform the prescriber if you have any signs or symptoms of liver problems as described in the Patient Guide. 14. Inform the prescriber immediately if you suspect you may be pregnant. 15. Inform the prescriber if there is a change in reproductive status.

3. Patients who cannot become pregnant who are prescribed FILSPARI:

Before treatment initiation	1. Review the Patient Guide. 2. Get a liver test. 3. Receive counseling from the prescriber on the risk of liver problems, the signs and symptoms of liver problems, the need to contact the prescriber if you have any signs or symptoms of liver problems, and the need to complete liver testing monthly for the first 12 months, then every 3 months during treatment using the Patient Guide. 4. Enroll in the REMS by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS.
During treatment; monthly for the first 12 months, then every 3 months	5. Get a liver test. 6. Adhere to the safe use condition: Communicate with the pharmacy to confirm completion of liver testing.
During treatment; monthly	7. Receive counseling from the pharmacy on the risk of liver problems associated with FILSPARI treatment.
At all times	8. Inform the prescriber if you have any signs or symptoms of liver problems as described in the Patient Guide. 9. Inform the prescriber if there is a change in reproductive status.

4. Outpatient pharmacies that dispense FILSPARI must:

To become certified to dispense	1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy. 2. Have the authorized representative review the Prescriber and Pharmacy Guide. 3. Have the authorized representative certify by enrolling in the REMS by completing the Outpatient Pharmacy Enrollment Form and submitting it to the REMS. 4. Train all relevant staff involved in dispensing on the REMS requirements using the Prescriber and Pharmacy Guide. 5. Establish processes and procedures to verify the patient is enrolled and the prescriber is certified. 6. Establish processes and procedures to document and submit confirmation of counseling on the risks of hepatotoxicity and embryo-fetal toxicity. 7. 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. 8. 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	9. Verify the patient is enrolled and the prescriber is certified through the processes and procedures established as a requirement of the REMS. 10. 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. 11. 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. 12. 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. 13. 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	14. Dispense no more than a 30-days' supply. 15. Report pregnancies to the REMS. 16. Report adverse events suggestive of hepatotoxicity to the REMS. 17. Not distribute, transfer, loan, or sell FILSPARI. 18. Maintain and submit records of product dispensing to the REMS. 19. Maintain records that all processes and procedures are in place and are being followed. 20. 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	21. Have a new authorized representative enroll by completing and submitting an Outpatient Pharmacy Enrollment Form, if the authorized representative changes.

5. Inpatient pharmacies that dispense FILSPARI must:

Become certified to dispense	1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy. 2. Have the authorized representative review the Prescriber and Pharmacy Guide. 3. Have the authorized representative certify by enrolling in the REMS by completing the Inpatient Pharmacy Enrollment Form and submitting it to the REMS. 4. Train all relevant staff involved in dispensing on the REMS requirements using the Prescriber and Pharmacy Guide. 5. 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. 6. For patients who can become pregnant: Establish processes and procedures to verify and document pregnancy testing is complete.

Before dispensing	7. 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. 8. 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. 9. 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. 10. For patients who can become pregnant: Verify and document pregnancy testing is complete.
At discharge	11. Dispense no more than a 30-days' supply.
At all times	12. Report pregnancies to the REMS. 13. Report adverse events suggestive of hepatotoxicity to the REMS. 14. Not distribute, transfer, loan, or sell FILSPARI. 15. Maintain records that all processes and procedures are in place and are being followed. 16. 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	17. Have a new authorized representative enroll by completing and submitting an Inpatient Pharmacy Enrollment Form, if the authorized representative changes.

6. Wholesalers-distributors that distribute FILSPARI must:	
To be able to distribute	1. Establish processes and procedures to ensure that FILSPARI is distributed only to certified pharmacies. 2. Train all relevant staff involved in distribution on the REMS requirements.
At all times	3. Distribute only to certified pharmacies. 4. Maintain and submit records of drug distribution to the REMS. 5. Maintain records that all processes and procedures are in place and are being followed. 6. 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.

Travere Therapeutics, Inc. must provide training to healthcare providers who prescribe FILSPARI.

The training includes the following educational material: Prescriber and Pharmacy Guide. The training must be available online and hard copy format via fax or mail.

Travere Therapeutics, Inc. must provide training to pharmacies that dispense FILSPARI.

The training includes the following educational material: Prescriber and Pharmacy Guide. The training must be available online and hard copy format via fax or mail.

To support REMS operations, Travere Therapeutics, Inc. must:

1. Authorize outpatient dispensing based on verifying the patient is enrolled and the prescriber is certified.
2. Establish and maintain a REMS Website, www.FILSPARIREMS.com. The REMS Website must include the capability to complete prescriber and inpatient pharmacy certification online, the capability to enroll and manage patients online, and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Website. The REMS Website must not link back to the promotional product website(s).
3. Make the REMS Website fully operational and all REMS materials available through the website and REMS Coordinating Center at the time FILSPARI first becomes commercially available.
4. Establish and maintain a REMS Coordinating Center for REMS participants at 1-833-513-1325.
5. Establish and maintain a validated, secure database of all REMS participants who are enrolled and certified in the REMS.

6. Ensure prescribers and inpatient pharmacies are able to complete the certification process by fax and online.

7. Ensure outpatient pharmacies are able to complete the certification process by fax.

8. Ensure prescribers are able to report change in reproductive status by fax and online.

9. Ensure prescribers are able to complete the patient enrollment process by fax and online.

10. Ensure pharmacies are able to verify the patient is enrolled and the prescriber is certified by phone and online.

11. Notify certified pharmacies of a patient's change or misclassification in reproductive status within one business day of receipt of a completed Change in Reproductive Potential Status Form.

12. Ensure pharmacies are able to enroll as inpatient (including, but not limited to, pharmacies in hospitals, long-term care facilities, prisons, and state psychiatric units) or outpatient pharmacies.

13. Notify prescribers and pharmacies of their REMS certification within one business day.

14. Provide the Prescriber Enrollment Form and the Prescriber and Pharmacy Guide to prescribers who (1) attempt to prescribe FILSPARI and are not yet certified or (2) inquire about how to become certified.

15. Provide certified prescribers access to the database of certified pharmacies and enrolled patients.

16. Provide certified pharmacies access to the database of certified prescribers and enrolled patients.

To ensure REMS participants' compliance with the REMS, Travere Therapeutics, Inc. must:

17. Verify the name and contact information of the pharmacy's authorized representative every 2 years. If different than the current authorized representative on file, the pharmacy is required to recertify with a new authorized representative.

18. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: FILSPARI distribution and dispensing; certification of prescribers and pharmacies; enrolled patients; and audits of REMS participants. These records must be readily available for FDA inspections.

19. Establish and maintain a plan for addressing non-compliance with REMS requirements.

20. Monitor prescribers, pharmacies, and wholesaler-distributors on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.

21. Audit all certified outpatient pharmacies and wholesaler-distributors within 180 calendar days after they become certified to ensure that all REMS processes and procedures are in place, functioning, and support the REMS requirements.

22. Audit annually: 1) all certified outpatient pharmacies, 2) a representative sample of inpatient pharmacies that have ordered FILSPARI in the past year, 3) all wholesaler-distributors, and 4) the REMS Coordinating Center to ensure that all the REMS processes and procedures are in place, functioning, and support the REMS requirements.

23. Take reasonable steps to improve operations of and compliance with the requirements in the REMS based on monitoring and evaluation of the REMS.

IV. REMS ASSESSMENT TIMETABLE

Travere Therapeutics, Inc. must submit REMS Assessments at 12 months, and annually from the date of the initial REMS approval (02/17/2023). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Travere Therapeutics, Inc. must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS MATERIALS

The following materials are part of the FILSPARI REMS:

Enrollment Forms

Prescriber:

1. Prescriber Enrollment Form

Patient:

2. Patient Enrollment Form

Pharmacy:

3. Outpatient Pharmacy Enrollment Form
4. Inpatient Pharmacy Enrollment Form

Training and Educational Materials

Prescriber:

5. Prescriber and Pharmacy Guide

Patient:

6. Patient Guide

Pharmacy:

7. Prescriber and Pharmacy Guide

Patient Care Form

8. Change in Reproductive Potential Status Form

Other Materials

9. REMS Website

VI. STATUTORY ELEMENTS

This REMS is required under section 505-1 of the Federal Food, Drug and Cosmetic Act (FD&C Act) and consists of the following elements:

1. Elements to Assure Safe Use
    - Health care providers who prescribe FILSPARI are specially certified under 505-1(f)(3)(A).
    - Pharmacies that dispense FILSPARI are specially certified under 505-1(f)(3)(B).
    - FILSPARI is dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D).
    - Each patient using FILSPARI is subject to certain monitoring under 505-1(f)(3)(E).
2. Implementation System
3. Timetable for Submission of Assessments

FILSPARI™ REMS PRESCRIBER ENROLLMENT FORM

To enroll in the FILSPARI REMS, complete and submit online at www.FILSPARIREMS.com or complete and fax this form to 1-833-483-4736.

1. Prescriber Information *(*indicates required field)*

*First Name:	Middle Initial:	*Last Name:
*National Provider Identifier (NPI) #:		
*Specialty (select one): ☐ Nephrology ☐ Other (please specify):_____		
*Professional Designation (select one): ☐ MD ☐ DO ☐ PA ☐ NP		
Office Practice/Clinic Name:		
*Address Line #1:		
Address Line #2:		
*City:	*State:	*Zip:
Preferred Method of Contact (select one): ☐ Fax ☐ Email	*Email:	
*Office Phone:	*Fax:	Mobile Phone:

Primary Office Contact Information

First Name:	Last Name:	
Address Line #1:		
Address Line #2:		
City:	State:	Zip:
Phone:	Fax:	
*Email (required if Office Contact is provided):		

Secondary Office Contact Information

First Name:	Last Name:	
Address Line #1:		
Address Line #2:		
City:	State:	Zip:
Phone:	Fax:	
*Email (required if Office Contact is provided):		

2. Prescriber Agreement *(*indicates required field)*

By signing this form, I agree to become certified in and comply with the following FILSPARI REMS requirements:

- Review the drug's Prescribing Information.
- Review the following: ***Prescriber and Pharmacy Guide***.
- Enroll in the REMS by completing the ***Prescriber Enrollment Form*** and submitting it to the REMS.

Before treatment initiation (first dose), I must:

- Counsel the patient on the risk of hepatotoxicity associated with FILSPARI, the signs and symptoms of liver problems, to contact the prescriber if the patient has any signs or symptoms of liver problems, on the REMS requirements including the need to complete liver testing monthly for the first 12 months, then every 3 months during treatment, and that FILSPARI is only available through a restricted distribution program using the ***Patient Guide***.
- Assess the patient's liver function. Document and submit to the REMS using the ***Patient Enrollment Form***.
- Assess the patient's reproductive status using the definitions in the ***Prescriber and Pharmacy Guide***. Document and submit to the REMS using the ***Patient Enrollment Form***.
- For patients who can become pregnant: Counsel the patient about the risk of embryo-fetal toxicity, the need to use effective contraception during treatment and for one month following treatment discontinuation, the need to complete monthly pregnancy tests, the potential need for emergency contraception, and to immediately contact their prescriber if the patient misses a menstrual period or if pregnancy is suspected using the ***Patient Guide***.
- For patients who can become pregnant: Assess the patient's pregnancy status by ordering a pregnancy test and reviewing the result. Document and submit to the REMS using the ***Patient Enrollment Form***.
- Provide the patient with the ***Patient Guide***.
- Enroll the patient by completing the ***Patient Enrollment Form*** and submitting it to the REMS.

During treatment; monthly for the first 12 months, then every 3 months, I must:

- Assess the patient's liver function.
- Counsel the patient on the risk of hepatotoxicity and if they are not complying with the required liver testing.

During treatment monthly, I must:

- For patients who can become pregnant: Assess the patient's pregnancy status by ordering a pregnancy test and reviewing the result.
- For patients who can become pregnant: Counsel the patient on the risk of embryo-fetal toxicity, to immediately contact their prescriber if they miss a menstrual period or if pregnancy is suspected, and counsel the patient if they are not complying with the required monthly pregnancy testing or if they are not using effective contraception.

After treatment discontinuation for one month, I must:

- For patients who can become pregnant: Assess the patient's pregnancy status by ordering a pregnancy test and reviewing the result.

At all times, I must:

- Report adverse events suggestive of hepatotoxicity to the REMS.
- Report pregnancies to the REMS.
- Assess the patient's reproductive status.

At all times, within 10 business days, I must:

- Report a change or misclassification in reproductive status to the REMS using the ***Change in Reproductive Potential Status Form***.

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

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FILSPARI™ REMS PATIENT ENROLLMENT FORM

To enroll in the FILSPARI REMS, complete and submit online at www.FILSPARIREMS.com or complete and fax this form to 1-833-483-4736.

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):		
*Primary Phone:	Other Phone:	Email:

2 Patient Agreement *(*indicates required field)*

PATIENTS WHO CAN BECOME PREGNANT

Before treatment, I must:
- Review the ***Patient Guide***.
- Get a liver test and a pregnancy test.
- Receive counseling from my prescriber on the risk of liver problems, the signs and symptoms of liver problems, the need to contact my prescriber if I have any signs or symptoms of liver problems, and the need to complete liver testing monthly for the first 12 months, then every 3 months during treatment using the ***Patient Guide***.
- Receive counseling from my prescriber on the risk of serious birth defects, the need to use effective contraception during treatment and for one month following treatment discontinuation, the need to complete monthly pregnancy tests, the potential need for emergency contraception, and to immediately contact my prescriber if I miss a menstrual period or suspect that I am pregnant using the ***Patient Guide***.
- Enroll in the REMS by completing the ***Patient Enrollment Form*** with my prescriber. Enrollment information will be provided to the REMS.

During treatment; monthly for the first 12 months, then 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.

During treatment monthly, I must:
- Get a pregnancy test.
- Receive counseling from the pharmacy on the risks of liver problems and serious birth defects associated with FILSPARI treatment.
- Adhere to the safe use condition: Communicate with the pharmacy to confirm completion of pregnancy testing.

During treatment and after treatment discontinuation for one month, I must:
- Adhere to the safe use condition: Use effective contraception as described in the ***Patient Guide***.

After treatment discontinuation for one month, I must:
- Get a pregnancy test.

At all times, I must:
- Inform my prescriber if I have any signs or symptoms of liver problems as described in the ***Patient Guide***.
- Inform my prescriber immediately if I suspect I may be pregnant.
- Inform my prescriber if there is a change in my reproductive status.

PATIENTS WHO CANNOT BECOME PREGNANT

Before treatment, I must:
- Review the ***Patient Guide***.
- Get a liver test.
- Receive counseling from my prescriber on the risk of liver problems, the signs and symptoms of liver problems, the need to contact the prescriber if I have any signs or symptoms of liver problems, and the need to complete liver testing monthly for the first 12 months, then every 3 months during treatment using the ***Patient Guide***.
- Enroll in the REMS by completing the ***Patient Enrollment Form*** with my prescriber. Enrollment information will be provided to the REMS.

During treatment; monthly for the first 12 months, then 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.

During treatment monthly, I must:
- 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***.
- Inform my prescriber if there is a change in my reproductive status.

*Patient Signature:		*Signature Date (MM-DD-YYYY):
*Parent/Legal Guardian Signature:		
Parent/Legal Guardian First Name (if signing on behalf of patient):	Parent/Legal Guardian Last Name:	Parent/Legal Guardian Email:

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3 Prescriber Information *(*indicates required field)*

*First Name:	*Last Name:

*National Provider Identifier (NPI) #:

4 Prescriber Authorization *(*indicates required field)*

***Please indicate the patient's current reproductive status below. (Please see definitions of these terms below)**

☐ **Patient Who Can Become Pregnant**

If selected, has a negative pregnancy test result been confirmed prior to prescribing FILSPARI?

☐ Yes

☐ No

Note: The pharmacy will confirm completion of a pregnancy test prior to each dispense

OR

☐ **Patient Who Cannot Become Pregnant**

***For this patient, have you reviewed the results of their current liver testing?** ☐ Yes ☐ No

Note: The pharmacy will confirm completion of a liver test prior to dispense

I certify that I have provided the appropriate counseling for patients and provided FILSPARI REMS materials. I will continue to fulfill my obligations under the FILSPARI REMS.

*Prescriber Signature:	*Signature Date (MM-DD-YYYY):

Definitions of Reproductive Potential Status

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 to the right).
- Other medical reasons for permanent, irreversible infertility.
- Patients without a uterus (including patients who were born male).

Patients Who Can Become Pregnant

- Patients with a uterus who have entered puberty and all patients who have a uterus and 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.

Menopause

Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or postsurgical from bilateral oophorectomy.

Prescriber Requirements Under the FILSPARI REMS

- I acknowledge that I have counseled the patient on the risk of hepatotoxicity and that FILSPARI is available only through a restricted distribution program under an FDA-required REMS using the ***Patient Guide***.
- I will assess the patient's liver function prior to initiation, monthly for the first 12 months, then every 3 months during treatment.
- I will evaluate the patient and agree to document any change in reproductive potential status by submitting a ***Change in Reproductive Potential Status Form*** within 10 business days of becoming aware of the change.

For Patients Who Can Become Pregnant

- I acknowledge that I have counseled the patient on the risk of embryo-fetal toxicity.
- I will assess the pregnancy status of the patient by ordering and reviewing a pregnancy test result prior to initiation, monthly during treatment prior to receiving each refill, and for one month after discontinuation of treatment in accordance with the FILSPARI REMS.

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.

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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:		

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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.

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FILSPARI™ REMS INPATIENT PHARMACY ENROLLMENT FORM

To become certified in the FILSPARI REMS, enroll by completing and submitting this form online at www.FILSPARIREMS.com or 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 inpatient pharmacies that wish to stock FILSPARI must certify by enrolling in the FILSPARI REMS.

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 inpatient 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. 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:	

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

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

3. Inpatient 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 ***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.
- For patients who can become pregnant: Establish processes and procedures to verify and document pregnancy 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.
- 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 is enrolled or will be enrolled prior to discharge, the patient is under the care of a certified prescriber, and liver testing is complete.
- For patients who can become pregnant: Verify and document pregnancy testing is complete.

At discharge, my pharmacy must:

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

At all times, my pharmacy must:

- Report pregnancies to the REMS.
- Report adverse events suggestive of hepatotoxicity to the REMS.
- Not distribute, transfer, loan, or sell FILSPARI.
- 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 ***Inpatient Pharmacy Enrollment Form***, if the authorized representative changes.

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

By signing below, you agree that you have read the above responsibilities and understand your obligations as an inpatient 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.

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FILSPARI™ REMS

PRESCRIBER AND PHARMACY GUIDE

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FILSPARI REMS

INDICATION

FILSPARI is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.

This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether FILSPARI slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

RISK OF HEPATOTOXICITY

Some Endothelin Receptor Antagonists (ERAs) have caused elevations of aminotransferases, hepatotoxicity, and liver failure. In clinical studies, elevations in aminotransferases (ALT or AST) of at least 3-times the Upper Limit of Normal (ULN) have been observed in up to 2.5% of FILSPARI-treated patients, including cases confirmed with rechallenge.

Initiate treatment with FILSPARI only after measuring aminotransferase levels and total bilirubin. Avoid initiation in patients with elevated aminotransferases (>3x ULN) because monitoring for hepatotoxicity in these patients may be more difficult and these patients may be at increased risk for serious hepatotoxicity.

Measure aminotransferase levels and total bilirubin prior to initiation of FILSPARI, monthly for the first 12 months after initiation, then every 3 months during treatment with FILSPARI.

RISK OF EMBRYO-FETAL TOXICITY

FILSPARI can cause major birth defects if used by pregnant patients based on animal data.

Initiate treatment with FILSPARI in patients who can become pregnant only after confirmation of a negative pregnancy test. Pregnancy tests are required monthly during treatment and one month after discontinuation of treatment with FILSPARI. Patients who can become pregnant must use effective contraception prior to initiation of treatment, during treatment, and for one month after discontinuation of treatment with FILSPARI.

FILSPARI REMS OVERVIEW

Due to the risks of hepatotoxicity and embryo-fetal toxicity, FILSPARI is only available to patients through a restricted distribution program under an FDA-required REMS, called the FILSPARI REMS.

The goal of the FILSPARI REMS is to mitigate the risks of hepatotoxicity and embryo-fetal toxicity associated with FILSPARI:

- Objective 1: Monitor for elevations in liver enzymes in patients exposed to FILSPARI
- Objective 2: Ensure that patients who can become pregnant are not pregnant before initiating FILSPARI
- Objective 3: Minimize exposure in patients who may become pregnant while taking FILSPARI

FILSPARI REMS REQUIREMENTS

- Prescribers must be certified in the FILSPARI REMS and comply with the REMS requirements to prescribe FILSPARI
- Pharmacies must be certified in the FILSPARI REMS and comply with the REMS requirements to dispense FILSPARI
- Patients must enroll in the FILSPARI REMS to receive FILSPARI
  - Patients must comply with liver testing requirements to receive FILSPARI
  - Patients who can become pregnant must comply with the pregnancy testing requirements to receive FILSPARI
- Prescribers must educate and counsel patients on the risks of FILSPARI, including hepatotoxicity and embryo-fetal toxicity using the ***Patient Guide***
- Prescribers must assess liver function for patients prior to initiation of FILSPARI, monthly for the first 12 months, then every 3 months during treatment to receive FILSPARI
- Prescribers must assess the patient's reproductive status using the definitions in this guide
- Prescribers must assess the pregnancy status of patients who can become pregnant by ordering and reviewing a pregnancy test result prior to initiation of FILSPARI treatment, monthly during treatment, and for one month after discontinuation of FILSPARI
- Prescribers must report any adverse events suggestive of hepatotoxicity and pregnancies that occur during treatment or within one month after discontinuation of FILSPARI to the FILSPARI REMS
- Prescribers must report any change or misclassification in a patient's reproductive potential status to the FILSPARI REMS within 10 business days of becoming aware of the change

SUMMARY OF THE FILSPARI REMS REQUIREMENTS BY PATIENT CATEGORY

Requirement	Patients Who Can Become Pregnant	Patients Who Cannot Become Pregnant
Prescriber enrolls patients into the FILSPARI REMS	✓	✓
Review and counsel using the ***Patient Guide***	✓	✓
Prescribers must order and review liver tests prior to initiation of treatment, monthly for the first 12 months, then every 3 months during treatment	✓	✓
Prescriber must order and review pregnancy tests prior to initiation of treatment, monthly during treatment, and for one month following treatment discontinuation	✓	
Prescriber must complete the ***Change in Reproductive Potential Status Form*** upon becoming aware of any change in reproductive status within 10 business days of becoming aware of the change	✓	✓

Reference ID: 5128838

ROLE OF PRESCRIBERS

Prescribers must complete the following steps to prescribe FILSPARI:

1. **Read the FILSPARI Prescribing Information and the *Prescriber and Pharmacy Guide* to understand the FILSPARI REMS and the risks of FILSPARI**
2. **Complete the *Prescriber Enrollment Form***
   - Prescribers will attest to understanding the risks of FILSPARI and agree to comply with the requirements of the FILSPARI REMS
   - Complete the form online at www.FILSPARIREMS.com or fax the completed form to 1-833-483-4736
3. **Assess liver function**
   - Order and review liver test results:
     - Prior to initiating treatment
     - Monthly for the first 12 months, then every 3 months during treatment

   The patient must agree to be contacted by the certified pharmacy prior to each shipment. The certified pharmacy will confirm the patient has completed their liver testing.
4. **Determine the reproductive status of patients**

   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)
   - Patients with other medical reasons for permanent, irreversible infertility
   - Patients without a uterus (including patients who were born male)

   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 below)
   - 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

   Definition of 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

Reference ID: 5128838

5. Assess pregnancy status in Patients Who Can Become Pregnant

- Order and review pregnancy test results:
  - Prior to initiating treatment
  - Monthly during treatment
  - One month following treatment discontinuation

The patient must agree to be contacted by the certified pharmacy prior to each shipment to confirm that they have completed a pregnancy test, and they must also understand that they will be contacted by the FILSPARI REMS if they become pregnant while on FILSPARI or within one month of stopping treatment.

6. Educate/counsel patients about the risks of FILSPARI and about the FILSPARI REMS

- Review and provide the ***Patient Guide*** prior to initiating treatment
- Counsel the patient about:
  - The risk of hepatotoxicity, the signs and symptoms of liver problems, the need to contact the prescriber if the patient has any signs or symptoms of liver problems, and on the REMS requirements including the need to complete liver testing monthly for the first 12 months, then every 3 months during treatment
  - FILSPARI is only available through a restricted distribution program called the FILSPARI REMS
- Counsel any patient who is not complying with the required liver testing

For Patients Who Can Become Pregnant:

- Review and provide the ***Patient Guide*** prior to initiating treatment
- Counsel the patient about:
  - The risk of embryo-fetal toxicity, the need to use effective contraception (see page 7) during treatment and for one month following treatment discontinuation, the need to complete monthly pregnancy tests, the potential need for emergency contraception, and to immediately contact the prescriber if the patient misses a menstrual period or pregnancy is suspected
- Counsel the patient if they are not complying with the required monthly pregnancy testing or if they are not using effective contraception

7. Enroll patients into the FILSPARI REMS

- Complete and submit the ***Patient Enrollment Form*** online at www.FILSPARIREMS.com or via fax to 1-833-483-4736

At all times, prescribers must:

- Notify the FILSPARI REMS of any adverse event suggestive of hepatotoxicity by calling 1-833-513-1325
- Notify the FILSPARI REMS if any patient becomes pregnant during FILSPARI treatment or within one month following treatment discontinuation by calling 1-833-513-1325
- Assess the patient's reproductive status
- Report a change or misclassification in reproductive status to the FILSPARI REMS within 10 business days of becoming aware of the change by completing a ***Change in Reproductive Potential Status Form*** online at www.FILSPARIREMS.com or by fax to 1-833-483-4736

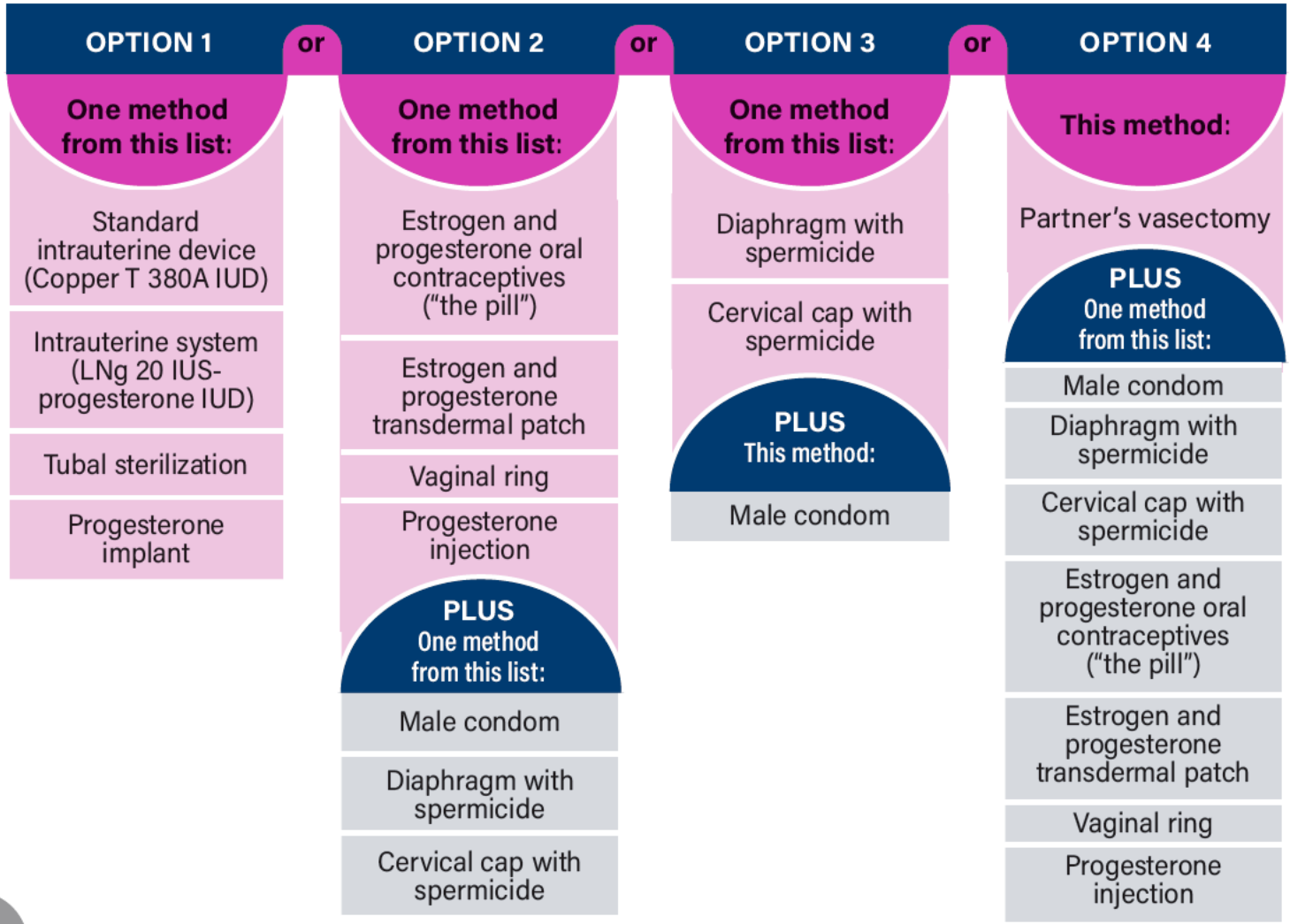
CONTRACEPTIVE OPTIONS FOR PATIENTS WHO CAN BECOME PREGNANT

Patients who can become pregnant should undergo contraceptive counseling with either the prescriber or another designated healthcare practitioner trained in contraceptive counseling.

Please refer to the diagram below for a complete list of the effective contraceptive options. The same diagram also appears in the ***Patient Guide*** and should be used to discuss effective birth control options with patients.

- Educate and counsel patients who can become pregnant on the use of emergency contraception in the event of unprotected sex or known or suspected contraceptive failure
- Remind patients to report to the prescriber immediately any delay in having a period or any other reason of suspected pregnancy during treatment
- If pregnancy is suspected for any reason, a pregnancy test must be performed
- **The prescriber must notify the FILSPARI REMS of any pregnancies that occur during treatment or within one month following treatment discontinuation**

Effective Birth Control Options



Reference ID: 5128838

ROLE OF CERTIFIED PHARMACIES

OUTPATIENT PHARMACY DISPENSING:

Only a limited number of certified pharmacies will dispense FILSPARI for outpatients. All outpatient pharmacies that wish to stock FILSPARI must contract with Travere Therapeutics, Inc.

To become certified to dispense FILSPARI, an outpatient 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, the outpatient pharmacy must:

- Verify the patient is enrolled and the prescriber is certified through the processes and procedures established as a requirement of the REMS
  - Outpatient pharmacies can verify by contacting the FILSPARI REMS online at www.FILSPARIREMS.com or by phone at 1-833-513-1325
- 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
  - Counsel the patient on the risk of hepatotoxicity, the signs and symptoms of liver problems, the need to contact the prescriber if they have any signs or symptoms of liver problems, and the need to complete liver testing
- 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
  - Counsel the patient on the risk of embryo-fetal toxicity, the need to use effective contraception during treatment and for one month following treatment discontinuation, the potential need for emergency contraception, the need to complete monthly pregnancy tests, and to inform the prescriber immediately if the patient misses a menstrual period or pregnancy is suspected
- 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
  - Confirm completion of liver testing prior to dispensing the first prescription, monthly for the first 12 months, then every 3 months during treatment
- 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
  - Confirm completion of pregnancy testing prior to dispensing the first prescription, and monthly during treatment

Reference ID: 5128838

ROLE OF CERTIFIED PHARMACIES

At all times, the outpatient pharmacy must:

- Dispense no more than a 30-days' supply
  - A certified prescriber may be eligible to provide the outpatient pharmacy a one-time authorization to dispense a greater than 30-days' supply. The outpatient pharmacy must report the reason to the FILSPARI REMS. For information on the eligibility to dispense more than a 30-days' supply and related authorization process, contact the FILSPARI REMS at 1-833-513-1325
- Report pregnancies to the REMS at 1-833-513-1325
- Report adverse events suggestive of hepatotoxicity to the REMS at 1-833-513-1325
- 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 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

INPATIENT PHARMACY DISPENSING:

Only inpatient pharmacies within institutions such as hospitals, long-term care facilities, and prisons that are certified in the FILSPARI REMS may stock FILSPARI for patients being treated in the inpatient setting.

To become certified to dispense FILSPARI, an inpatient 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 ***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
- For patients who can become pregnant: Establish processes and procedures to verify and document pregnancy testing is complete

Reference ID: 5128838

ROLE OF CERTIFIED PHARMACIES continued

Before dispensing FILSPARI, the inpatient 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
  - Counsel the patient on the risk of hepatotoxicity, the signs and symptoms of liver problems, the need to contact the prescriber if they have any signs or symptoms of liver problems, and the need to complete liver testing
- 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
  - Counsel the patient on the risk of embryo-fetal toxicity, the need to use effective contraception during treatment and for one month following treatment discontinuation, the potential need for emergency contraception, the need to complete monthly pregnancy tests, and to inform the prescriber immediately if the patient misses a menstrual period or pregnancy is suspected
- 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
  - Liver testing will be required monthly for the first 12 months, then every 3 months during treatment
- For patients who can become pregnant: Verify and document pregnancy testing is complete
  - Pregnancy testing will be required monthly and for one month following treatment discontinuation

At discharge, the inpatient pharmacy must:

- Dispense no more than a 30-days' supply

At all times, the inpatient pharmacy must:

- Report pregnancies to the REMS
- Report adverse events suggestive of hepatotoxicity to the REMS
- Not distribute, transfer, loan, or sell FILSPARI
- 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 ***Inpatient Pharmacy Enrollment Form***, if the authorized representative changes

For a list of Certified Pharmacies, call the FILSPARI REMS at 1-833-483-4736.

THE FILSPARI REMS COORDINATING CENTER

- Enters every FILSPARI certified prescriber, enrolled patient, and enrolled pharmacy into the FILSPARI REMS database
- Collects all ***Patient Enrollment Forms***, ***Prescriber Enrollment Forms***, ***Pharmacy Enrollment Forms (Outpatient and Inpatient)***, and ***Change in Reproductive Potential Status Forms***
- Allows access to the FILSPARI REMS database to the certified pharmacies for verification of patient and prescriber information
- Collects information about changes in reproductive status, and any occurrences of pregnancies during FILSPARI treatment or within one month following treatment discontinuation

Notes

Reference ID: 5128838

ADDITIONAL QUESTIONS

Please visit www.FILSPARIREMS.com or call the FILSPARI REMS at 1-833-513-1325 for more information about the FILSPARI REMS.

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.

Phone: 1-833-513-1325
www.FILSPARIREMS.com
Fax: 1-833-483-4736

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FILSPARI™ REMS

PATIENT GUIDE

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INFORMATION FOR PATIENTS

WHAT IS FILSPARI?

FILSPARI is a prescription medicine used to reduce levels of protein in the urine (proteinuria) in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN), who are at high risk of disease progression.

WHAT ARE THE SERIOUS RISKS OF FILSPARI?

FILSPARI can cause liver problems. Patients must have their liver function checked before starting FILSPARI, monthly for the first 12 months, then every 3 months during treatment with FILSPARI.

FILSPARI can cause serious birth defects if taken during pregnancy. Patients must not be pregnant when they start taking FILSPARI or become pregnant during treatment with FILSPARI, or for one month after stopping FILSPARI.

WHAT IS THE FILSPARI RISK EVALUATION AND MITIGATION STRATEGY (REMS)?

Because of the risk of liver problems and serious birth defects, the Food and Drug Administration (FDA) has required a program called a Risk Evaluation and Mitigation Strategy (REMS) for FILSPARI. The purpose of the FILSPARI REMS is to make sure the benefits of FILSPARI outweigh the risks. Patients must enroll in the FILSPARI REMS to receive FILSPARI.

Reference ID: 5128838

HOW DO I ENROLL AND TAKE PART IN THE FILSPARI REMS?

- Read the patient information about FILSPARI and the FILSPARI REMS included in this guide or on the ***REMS Website***, www.FILSPARIREMS.com
- Talk with your prescriber to ensure the benefits outweigh the risks of FILSPARI
- Ask questions. Make sure you understand the benefits and risks and what you need to do to enroll and take part in the FILSPARI REMS. Make sure you know how to receive and take FILSPARI
- Before starting FILSPARI:
  - Get a liver test
  - Get a pregnancy test if you are a patient who can become pregnant
- During treatment:
  - Get a liver test every month for the first 12 months, then every 3 months
  - Get a pregnancy test every month if you are a patient who can become pregnant
- One month after stopping FILSPARI:
  - Get a pregnancy test if you are a patient who can become pregnant
- You and your prescriber need to choose a certified pharmacy to supply FILSPARI. In some cases, your insurance company may need you to use a specific certified pharmacy
- You and your prescriber must fill out the ***Patient Enrollment Form***. After you read and sign it, your prescriber will send it to the FILSPARI REMS
- Your prescription will be mailed to you from a certified pharmacy

WHAT ARE THE FILSPARI REMS REQUIREMENTS FOR ME?

To receive FILSPARI, you must:

- Talk to your prescriber to ensure the benefits outweigh the risks of FILSPARI
- Get a liver test before starting FILSPARI, monthly for the first 12 months, then every 3 months during treatment
- Receive counseling from your prescriber on the risk of liver problems using the ***Patient Guide***
- Enroll in the FILSPARI REMS by completing and signing the ***Patient Enrollment Form***
- **Be sure you get your liver test monthly for the first 12 months, then every 3 months during treatment. Your certified pharmacy will call you to provide counseling and confirm completion of a liver test before shipping your refill. If you do not get your liver test, you may not receive your FILSPARI on time**

Patients Who Can Become Pregnant:

You are considered to be a patient who can become pregnant if you have entered puberty, have a uterus, and have not gone through menopause.

To receive FILSPARI, you must:

- Talk to your prescriber to ensure the benefits outweigh the risks of FILSPARI
- Get a pregnancy test before you start taking FILSPARI and before you receive your refills. Your prescriber will order your monthly pregnancy tests during treatment and for one month after discontinuing treatment
- Receive counseling from your prescriber on the risk of of serious birth defects using the ***Patient Guide***
- Enroll in the FILSPARI REMS by completing the ***Patient Enrollment Form***
- **Be sure you get your monthly pregnancy test. Your certified pharmacy will call you to provide counseling and confirm completion of a pregnancy test before shipping your refill. If you do not get your monthly pregnancy test, you may not receive your FILSPARI on time**
- Understand that you will be contacted by the FILSPARI REMS if you become pregnant while on FILSPARI or within one month of stopping treatment

Do not have unprotected sex or sexual contact (penis-vaginal) with a partner who can get you pregnant. Use effective birth control during your FILSPARI treatment and for one month after stopping your FILSPARI treatment because the medicine may still be in your body. Page 6 of this guide shows your birth control options.

Talk to your prescriber or pharmacist right away if you have unprotected sex, if you think your birth control has failed, or if you think you may be pregnant. Your prescriber may tell you to use emergency birth control. Do not wait until your next appointment to tell your prescriber if there is any delay in having a period or any other reason you think you may be pregnant.

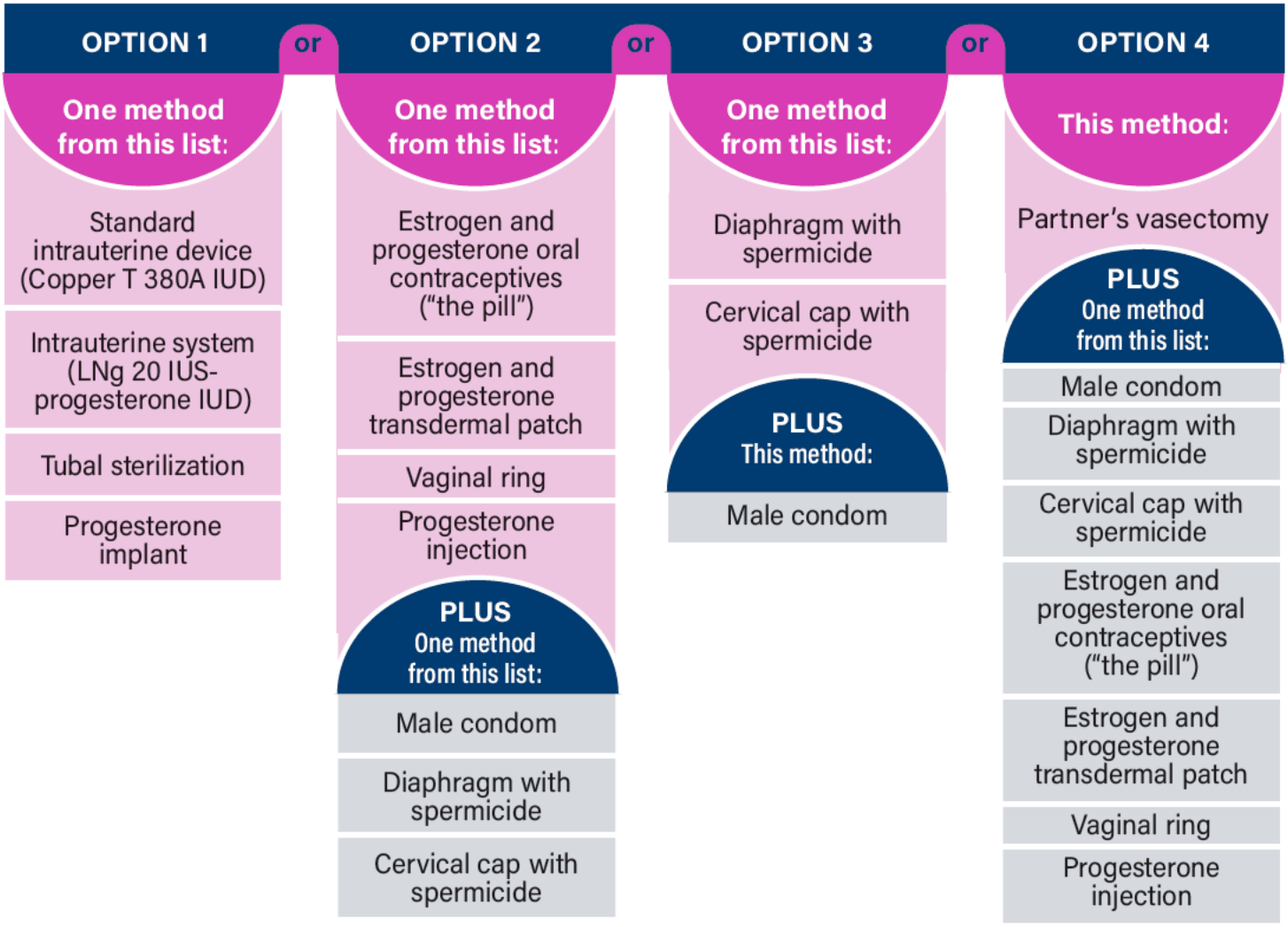
Reference ID: 5128838

WHAT ARE MY BIRTH CONTROL OPTIONS IF I CAN BECOME PREGNANT?

If you are a patient who can become pregnant, your prescriber will talk to you about your birth control options before starting FILSPARI. Use the diagram below to help decide what birth control options are best for you. Talk to your prescriber if you have questions about your birth control options. Tell your prescriber if you want to change your birth control method.

You may choose from the four options listed below. More than one birth control method might be needed every time you have sex.

Effective Birth Control Options



HOW WILL I RECEIVE MY FILSPARI?

Only pharmacies that are certified in the FILSPARI REMS can provide FILSPARI to you. In some cases, your insurance company may require you to use a specific certified pharmacy.

Your certified pharmacy ships your FILSPARI refill to you. Before each shipment, the certified pharmacy will confirm that you have completed a liver test (monthly for the first 12 months, then every 3 months during treatment) and completed a pregnancy test (monthly) if you are a patient who can become pregnant before refilling your prescription. **It is important that your certified pharmacy is able to contact you in order to avoid delays in your refills.**

REMINDERS

- **Get a liver test before starting FILSPARI, monthly for the first 12 months, then every 3 months during treatment**
- **Tell the certified pharmacy when they call whether you completed your liver test**
- **Tell your healthcare provider right away if you have any of these symptoms of liver problems while taking FILSPARI:**
  - **Nausea**
  - **Vomiting**
  - **Pain on the upper right side of your stomach area**
  - **Tiredness**
  - **Loss of appetite**
  - **Yellowing of the skin or the whites of your eyes (jaundice)**
  - **Dark "tea-colored" urine**
  - **Fever**
  - **Itching**

REMINDERS FOR PATIENTS WHO CAN BECOME PREGNANT

- **Do not get pregnant**
- **Always use effective birth control while taking FILSPARI and for one month after you stop**
- **Get a pregnancy test before starting FILSPARI, every month during treatment, and one month after discontinuing treatment**
- **Tell the certified pharmacy when they call whether you have completed your pregnancy test**
- **Tell your healthcare provider right away if you:**
  - **Have unprotected sex**
  - **Miss a menstrual period**
  - **Think your birth control has failed**
  - **Think you may be pregnant**

If you have questions or concerns about FILSPARI, talk to your healthcare provider.
Please visit **www.FILSPARIREMS.com** or call **1-833-513-1325** Monday through Friday from 8 AM EST to 8 PM EST for more information about the FILSPARI REMS.

FILSPARI™
(sparsentan) tablets
200 mg/400 mg

Approval: MM/YY

FILSPARI™ REMS

CHANGE IN REPRODUCTIVE POTENTIAL STATUS FORM

Complete and submit online at www.FILSPARIREMS.com or complete and fax this form to 1-833-513-1325.

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

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

Approval: MM/YY

FILSPARI™ (sparsentan) tablets 200 mg/400 mg

THE FILSPARI™ REMS (RISK EVALUATION AND MITIGATION STRATEGY)

The FILSPARI REMS is a safety program that manages the risks of liver problems and serious birth defects when taking FILSPARI. The FILSPARI REMS is required by the Food and Drug Administration (FDA).

The goal of the FILSPARI REMS is to mitigate the risks of hepatotoxicity and embryo-fetal toxicity associated with FILSPARI:

- Objective 1: Monitor for elevations in liver enzymes in patients exposed to FILSPARI
- Objective 2: Ensure that patients who can become pregnant are not pregnant before initiating FILSPARI
- Objective 3: Minimize exposure in patients who may become pregnant while taking FILSPARI

Prescribers

Click here to learn how to prescribe FILSPARI

To prescribe FILSPARI:

1. **Review** the Prescribing Information and ***Prescriber and Pharmacy Guide***
2. **Certify** by enrolling in the FILSPARI REMS by completing the ***Prescriber Enrollment Form*** and submitting it to the FILSPARI REMS
3. **Counsel** patients on the risks associated with FILSPARI using the ***Patient Guide***
4. **Assess** the patient's liver function
5. **Assess** the patient's reproductive status as defined in the ***Prescriber and Pharmacy Guide***
6. **Assess** pregnancy status in patients who can become pregnant
7. **Enroll** patients in the FILSPARI REMS by completing and submitting the ***Patient Enrollment Form*** to the FILSPARI REMS
8. **Monitor** patients based on REMS requirements
9. **Report** any changes in the reproductive status of a patient via the ***Change in Reproductive Potential Status Form***

Resources for Prescribers

- ***Prescriber and Pharmacy Guide***
- ***Prescriber Enrollment Form***
- ***Patient Enrollment Form*** English, Spanish, Chinese
- ***Patient Guide*** English, Spanish, Chinese
- ***Change in Reproductive Potential Status Form***

Patients

Click here to learn how to receive FILSPARI

To receive FILSPARI:

1. **Review** the ***Patient Guide***
2. **Get** a liver test prior to initiating FILSPARI, monthly for the first 12 months, then every 3 months during treatment
3. For patients who can become pregnant:
   - **Get** a pregnancy test prior to initiating FILSPARI, monthly during treatment, and one month after discontinuing treatment
   - **Use** effective birth control while taking FILSPARI and for one month after treatment discontinuation
4. **Receive** counseling from your prescriber at treatment initiation and from the outpatient pharmacy prior to refills to understand the risks associated with FILSPARI
5. **Enroll** in the FILSPARI REMS by completing the ***Patient Enrollment Form*** with your prescriber

Resources for Patients

- ***Patient Guide*** English, Spanish, Chinese

Outpatient Pharmacies

Click here to learn how to dispense FILSPARI

To dispense FILSPARI:

1. **Designate** an authorized representative to carry out the certification process and oversee implementation and compliance with the FILSPARI REMS on behalf of the pharmacy
2. **Have** the authorized representative review the ***Prescriber and Pharmacy Guide***
3. **Have** the authorized representative certify by enrolling in the FILSPARI REMS by completing the ***Outpatient Pharmacy Enrollment Form***, and submitting it to the FILSPARI REMS
4. **Train** staff involved in dispensing FILSPARI and comply with REMS requirements
5. **Before dispensing**:
   - **Contact** the FILSPARI REMS online or by phone to verify the patient is enrolled in the FILSPARI REMS and the prescriber is certified
   - **Counsel** the patient on the risks associated with FILSPARI
   - **Verify** and document the patient's liver testing is complete or the prescriber authorizes the refill, and the reproductive status has not changed
   - **Verify** and document pregnancy testing is complete for patients who can become pregnant or the prescriber authorizes the refill
6. **Dispense** no more than a 30-days' supply
7. **Provide** dispensing data to the FILSPARI REMS

Resources for Outpatient Pharmacies

- ***Prescriber and Pharmacy Guide***
- ***Outpatient Pharmacy Enrollment Form***
- ***Patient Guide*** English, Spanish, Chinese

Inpatient Pharmacies

Click here to learn how to dispense FILSPARI

To dispense FILSPARI:

1. **Designate** an authorized representative to carry out the certification process and oversee implementation and compliance with the FILSPARI REMS on behalf of the pharmacy
2. **Have** the authorized representative review the ***Prescriber and Pharmacy Guide***
3. **Have** the authorized representative certify by enrolling in the FILSPARI REMS by completing the ***Inpatient Pharmacy Enrollment Form***, and submitting it to the FILSPARI REMS
4. **Train** staff involved in dispensing FILSPARI and comply with REMS requirements
5. **Before dispensing**:
   - **Counsel** the patient on the risks associated with FILSPARI
   - **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
   - **Verify** and document pregnancy testing is complete for patients who can become pregnant
6. **Dispense** no more than a 30-days' supply at discharge

Resources for Inpatient Pharmacies

- ***Prescriber and Pharmacy Guide***
- ***Inpatient Pharmacy Enrollment Form***
- ***Patient Guide*** English, Spanish, Chinese

To learn more about the serious risks associated with FILSPARI, please refer to the **US Prescribing Information including Boxed Warning**, the ***Prescriber and Pharmacy Guide*** and the ***Patient Guide***.

Prescribers

Only prescribers certified by the FILSPARI REMS can prescribe FILSPARI and only pharmacies certified by the FILSPARI REMS can dispense FILSPARI to patients.

Patients must be enrolled in the FILSPARI REMS and follow all the safety rules in the FILSPARI REMS in order to receive FILSPARI.

Prescriber Requirements

How do I become certified in the FILSPARI REMS?

1. Review the following educational materials to understand the FILSPARI REMS and the risks of FILSPARI:
   - **Prescribing Information**
   - ***Prescriber and Pharmacy Guide***
2. Complete and submit the ***Prescriber Enrollment Form:***
   - **Online**
   - **By fax**

How do I enroll my patient in the FILSPARI REMS and what steps should I take prior to treatment initiation?

1. Counsel the patient on the risk of hepatotoxicity associated with FILSPARI, the signs and symptoms of liver problems, to contact the prescriber if the patient has any signs or symptoms of liver problems, on the REMS requirements including the need to complete liver testing monthly for the first 12 months, then every 3 months during treatment, and that FILSPARI is only available through a restricted distribution program using the ***Patient Guide***.
2. Assess the patient's liver function. Document and submit to the REMS using the ***Patient Enrollment Form***.
3. Assess the patient's reproductive status using the definitions in the ***Prescriber and Pharmacy Guide***. Document and submit to the REMS using the ***Patient Enrollment Form***.
4. For patients who can become pregnant:
   - Counsel the patient about the risk of embryo-fetal toxicity, the need to use effective contraception during treatment and for one month following treatment discontinuation, the need to complete monthly pregnancy tests, the potential need for emergency contraception, and to immediately contact their prescriber if the patient misses a menstrual period or if pregnancy is suspected using the ***Patient Guide***.
   - Assess the patient's pregnancy status by ordering a pregnancy test and reviewing the result. Document and submit to the REMS using the ***Patient Enrollment Form***.
5. Provide the patient with the ***Patient Guide***.
6. Enroll the patient by completing the ***Patient Enrollment Form*** and submitting it to the REMS:
   - **Online**
   - **By fax**

Once a patient is on FILSPARI, how often should I monitor my patient?

- Assess the patient's liver function monthly for the first 12 months, then every 3 months during treatment.
- For a patient who can become pregnant: Assess the patient's pregnancy status by ordering a pregnancy test and reviewing the result monthly during treatment and for one month after discontinuation.
- Report any adverse events suggestive of hepatotoxicity to the REMS.
- Report pregnancies to the REMS.
- Assess the patient's reproductive status.
- Report a change or misclassification in reproductive status to the FILSPARI REMS using the ***Change in Reproductive Potential Status Form*** within 10 days of being aware of a change:
  - **Online**
  - **By fax**

PDFs for Download

Resources for Prescribers

Prescriber and Pharmacy Guide

Prescriber Enrollment Form

Patient Enrollment Form
English
Spanish
Chinese

Patient Guide
English
Spanish
Chinese

Change in Reproductive Potential Status Form

FILSPARI™ REMS PRESCRIBER ENROLLMENT FORM

To enroll in the FILSPARI REMS, please complete all fields below and submit this form.

* *Indicates required field*

1 Prescriber Information

*National Provider Identifier (NPI) #

CONTINUE

FILSPARI™ REMS PRESCRIBER ENROLLMENT FORM

To enroll in the FILSPARI REMS, please complete all fields below and submit this form.

* *Indicates required field*

1 Prescriber Information

*National Provider Identifier (NPI) #

1234567890

*First Name | Middle Initial | *Last Name

*Specialty (select one)
- ○ Nephrology
- ○ Other (please specify)

*Professional Designation (select one)
- ○ MD ○ DO ○ PA ○ NP

Office Practice/Clinic Name

*Address Line #1 | Address Line #2

*City | *State (-- Please Select --) | *Zip

Preferred Method of Contact (select one)
- ○ Fax ○ Email

*Email | *Office Phone | *Fax | Mobile Phone

Primary Office Contact Information

First Name | Last Name

Address Line #1 | Address Line #2

City | State (-- Please Select --) | Zip

Email | Phone | Fax

Secondary Office Contact Information

First Name | Last Name

Address Line #1 | Address Line #2

City | State (-- Please Select --) | Zip

Email | Phone | Fax

2 Prescriber Agreement

By signing this form, I agree to become certified in and comply with the following FILSPARI REMS requirements:

- Review the drug's Prescribing Information
- Review the following: ***Prescriber and Pharmacy Guide***.
- Enroll in the REMS by completing the ***Prescriber Enrollment Form*** and submitting it to the REMS.

Before treatment initiation (first dose), I must:

- Counsel the patient on the risk of hepatotoxicity associated with FILSPARI, the signs and symptoms of liver problems, to contact the prescriber if the patient has any signs or symptoms of liver problems, on the REMS requirements including the need to complete liver testing monthly for the first 12 months, then every 3 months during treatment, and that FILSPARI is only available through a restricted distribution program using the ***Patient Guide***.
- Assess the patient's liver function. Document and submit to the REMS using the ***Patient Enrollment Form***.
- Assess the patient's reproductive status using the definitions in the ***Prescriber and Pharmacy Guide***. Document and submit to the REMS using the ***Patient Enrollment Form***.
- For patients who can become pregnant: Counsel the patient about the risk of embryo-fetal toxicity, the need to use effective contraception during treatment and for one month following treatment discontinuation, the need to complete monthly pregnancy tests, the potential need for emergency contraception, and to immediately contact their prescriber if the patient misses a menstrual period or if pregnancy is suspected using the ***Patient Guide***.
- For patients who can become pregnant: Assess the patient's pregnancy status by ordering a pregnancy test and reviewing the result. Document and submit to the REMS using the ***Patient Enrollment Form.***
- Provide the patient with the ***Patient Guide***.
- Enroll the patient by completing the ***Patient Enrollment Form*** and submitting it to the REMS.

During treatment; monthly for the first 12 months, then every 3 months, I must:

- Assess the patient's liver function.
- Counsel the patient on the risk of hepatotoxicity and if they are not complying with the required liver testing.

During treatment monthly, I must:

- For patients who can become pregnant: Assess the patient's pregnancy status by ordering a pregnancy test and reviewing the result.
- For patients who can become pregnant: Counsel the patient on the risk of embryo-fetal toxicity, to immediately contact their prescriber if they miss a menstrual period or if pregnancy is suspected, and counsel the patient if they are not complying with the required monthly pregnancy testing or if they are not using effective contraception.

After treatment discontinuation for one month, I must:

- For patients who can become pregnant: Assess the patient's pregnancy status by ordering a pregnancy test and reviewing the result.

At all times, I must:

- Report adverse events suggestive of hepatotoxicity to the REMS.
- Report pregnancies to the REMS.
- Assess the patient's reproductive status.

At all times, within 10 business days, I must:

- Report a change or misclassification in reproductive status to the REMS using the ***Change in Reproductive Potential Status Form***.

☐ *Prescriber Signature

CLEAR | CANCEL | SUBMIT

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.

FILSPARI™ REMS PRESCRIBER ENROLLMENT FORM

To enroll in the FILSPARI REMS, please complete all fields below and submit this form.

* *Indicates required field*

1 Prescriber Information

*National Provider Identifier (NPI) #

1234567890

*First Name | Middle Initial | *Last Name

*Specialty (select one)
- Nephrology
- Other (please specify)

*Professional Designation (select one)
- MD
- DO
- PA
- NP

*Other Specialty

Other

Office Practice/Clinic Name

*Address Line #1 | Address Line #2

*City | *State | *Zip

-- Please Select --

Preferred Method of Contact (select one)
- Fax
- Email

*Email | *Office Phone | *Fax | Mobile Phone

Primary Office Contact Information

First Name | Last Name

Address Line #1 | Address Line #2

City | State | Zip

-- Please Select --

Email | Phone | Fax

Secondary Office Contact Information

First Name | Last Name

Address Line #1 | Address Line #2

City | State | Zip

-- Please Select --

Email | Phone | Fax

2 Prescriber Agreement

By signing this form, I agree to become certified in and comply with the following FILSPARI REMS requirements:

- Review the drug's Prescribing Information
- Review the following: ***Prescriber and Pharmacy Guide***.
- Enroll in the REMS by completing the ***Prescriber Enrollment Form*** and submitting it to the REMS.

Before treatment initiation (first dose), I must:

- Counsel the patient on the risk of hepatotoxicity associated with FILSPARI, the signs and symptoms of liver problems, to contact the prescriber if the patient has any signs or symptoms of liver problems, on the REMS requirements including the need to complete liver testing monthly for the first 12 months, then every 3 months during treatment, and that FILSPARI is only available through a restricted distribution program using the ***Patient Guide***.
- Assess the patient's liver function. Document and submit to the REMS using the ***Patient Enrollment Form***.
- Assess the patient's reproductive status using the definitions in the ***Prescriber and Pharmacy Guide***. Document and submit to the REMS using the ***Patient Enrollment Form***.
- For patients who can become pregnant: Counsel the patient about the risk of embryo-fetal toxicity, the need to use effective contraception during treatment and for one month following treatment discontinuation, the need to complete monthly pregnancy tests, the potential need for emergency contraception, and to immediately contact their prescriber if the patient misses a menstrual period or if pregnancy is suspected using the ***Patient Guide***.
- For patients who can become pregnant: Assess the patient's pregnancy status by ordering a pregnancy test and reviewing the result. Document and submit to the REMS using the ***Patient Enrollment Form.***
- Provide the patient with the ***Patient Guide***.
- Enroll the patient by completing the ***Patient Enrollment Form*** and submitting it to the REMS.

During treatment; monthly for the first 12 months, then every 3 months, I must:

- Assess the patient's liver function.
- Counsel the patient on the risk of hepatotoxicity and if they are not complying with the required liver testing.

During treatment monthly, I must:

- For patients who can become pregnant: Assess the patient's pregnancy status by ordering a pregnancy test and reviewing the result.
- For patients who can become pregnant: Counsel the patient on the risk of embryo-fetal toxicity, to immediately contact their prescriber if they miss a menstrual period or if pregnancy is suspected, and counsel the patient if they are not complying with the required monthly pregnancy testing or if they are not using effective contraception.

After treatment discontinuation for one month, I must:

- For patients who can become pregnant: Assess the patient's pregnancy status by ordering a pregnancy test and reviewing the result.

At all times, I must:

- Report adverse events suggestive of hepatotoxicity to the REMS.
- Report pregnancies to the REMS.
- Assess the patient's reproductive status.

At all times, within 10 business days, I must:

- Report a change or misclassification in reproductive status to the REMS using the ***Change in Reproductive Potential Status Form***.

☐ *Prescriber Signature

CLEAR | CANCEL | SUBMIT

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.

Prescriber Enrollment Submitted Successfully

Thank you for submitting your information to enroll in the FILSPARI REMS.

A confirmation of this submission has been sent to the email address provided. This email will also include instructions on how to create your web account for the FILSPARI REMS.

If you do not receive the email within the next few hours or would like to update your enrollment information at any time, please contact the FILSPARI REMS for assistance at 1-833-513-1325.

Patients

What is FILSPARI?

FILSPARI is a prescription medicine used to reduce levels of protein in the urine (proteinuria) in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN), who are at high risk of disease progression.

What are the serious risks of FILSPARI?

FILSPARI can cause liver problems. Patients must have their liver function checked before starting FILSPARI, monthly for the first 12 months, then every 3 months during treatment with FILSPARI.

FILSPARI can cause serious birth defects if taken during pregnancy. Patients must not be pregnant when they start taking FILSPARI or become pregnant during treatment with FILSPARI, or for one month after stopping FILSPARI.

How do I become enrolled in the FILSPARI REMS?

1. **Read** the ***Patient Guide***.
2. **Review** and discuss the benefits and risks associated with FILSPARI with your prescriber.
3. **Enroll** in the FILSPARI REMS by completing the ***Patient Enrollment Form*** with your prescriber.

Please refer to the details provided below and in the ***Patient Guide*** for REMS requirements.

What are the FILSPARI REMS requirements for me?

To receive FILSPARI, you must:

- Talk to your prescriber to ensure the benefits outweigh the risks of FILSPARI.
- Receive counseling from your prescriber on the risk of liver problems using the ***Patient Guide***.
- Enroll in the FILSPARI REMS by completing and signing the ***Patient Enrollment Form***.
- Get a liver test before starting FILSPARI, every month for the first 12 months, then every 3 months during treatment.
- **Be sure you get your liver test monthly for the first 12 months, then every 3 months during treatment. Your certified pharmacy will call you to provide counseling and confirm completion of a liver test before shipping your refill. If you do not get your liver test, you may not receive your FILSPARI on time.**

If you are a patient who can become pregnant:

You are considered to be a patient who can become pregnant if you have entered puberty, have a uterus, but have not gone through menopause.

To receive FILSPARI, you must:

- Talk to your prescriber to ensure the benefits outweigh the risks of FILSPARI.
- Receive counseling from your prescriber on the risk of serious birth defects using the ***Patient Guide***.
- Enroll in the FILSPARI REMS by completing the ***Patient Enrollment Form***.
- Get a pregnancy test before you start taking FILSPARI and before you receive your refills. Your prescriber will order your monthly pregnancy tests during treatment and for one month after discontinuing treatment.
- **Be sure to get your monthly pregnancy test. Your certified pharmacy will call you every month to provide counseling and confirm completion of pregnancy testing before shipping your refill. If you do not get your pregnancy test, you may not receive your FILSPARI on time.**
- Understand that you will be contacted by the FILSPARI REMS if you become pregnant while on FILSPARI or within one month of stopping treatment.

Do not have unprotected sex or sexual contact (penis-vaginal) with a partner who can get you pregnant. Use effective birth control during your FILSPARI treatment and for one month after stopping your FILSPARI treatment because the medicine may still be in your body.

Talk to your prescriber or pharmacist right away if you have unprotected sex, if you think your birth control has failed, or if you think you may be pregnant. Your prescriber may tell you to use emergency birth control. Do not wait until your next appointment to tell your prescriber if there is any delay in having a period or any other reason you think you may be pregnant.

What are my birth control options?

If you are a patient who can become pregnant, your prescriber will talk to you about your birth control options before starting FILSPARI. Use the diagram below to help decide what birth control options are best for you. Talk to your prescriber if you have questions about your birth control options. Tell your prescriber if you want to change your birth control method.

You may choose from the four options listed below. More than one birth control method might be needed every time you have sex.

Effective Birth Control Options

OPTION 1	OR	OPTION 2	OR	OPTION 3	OR	OPTION 4
One method from this list:		One method from this list:		One method from this list:		This method:
Standard intrauterine device (Copper T 380A IUD)		Estrogen and progesterone oral contraceptives ("the pill")		Diaphragm with spermicide		Partner's vasectomy
Intrauterine system (LNg 20 IUS-progesterone IUD)		Estrogen and progesterone transdermal patch		Cervical cap with spermicide		PLUS One method from this list:
Tubal sterilization		Vaginal ring		PLUS This method:		Male condom
Progesterone implant		Progesterone injection		Male condom		Diaphragm with spermicide
		PLUS One method from this list:				Cervical cap with spermicide
		Male condom				Estrogen and progesterone oral contraceptives ("the pill")
		Diaphragm with spermicide				Estrogen and progesterone transdermal patch
		Cervical cap with spermicide				Vaginal ring
						Progesterone injection

How will I receive my FILSPARI?

Only pharmacies that are certified in the FILSPARI REMS can provide FILSPARI to you. In some cases, your insurance company may require you to use a specific certified pharmacy.

Your certified pharmacy ships your FILSPARI refill to you. Before each shipment, the certified pharmacy will confirm that you have completed a liver test (monthly for the first 12 months, then every 3 months during treatment) and completed a pregnancy test (monthly) if you are a patient who can become pregnant before refilling your prescription. **It is important that your certified pharmacy is able to contact you in order to avoid delays in your refills**.

If you have questions or concerns about FILSPARI, talk to your prescriber. Please visit **www.FILSPARIREMS.com** or call **1-833-513-1325** for more information about the FILSPARI REMS.

PDFs for Download

Resources for Patients

Patient Guide
English
Spanish
Chinese

Outpatient Pharmacies

Only a limited number of certified pharmacies will dispense FILSPARI for outpatients. All outpatient pharmacies that wish to stock FILSPARI must contract with Travere Therapeutics, Inc., and must have the authorized representative certify by enrolling in the FILSPARI REMS.

Contact the FILSPARI REMS to obtain contact information for certified outpatient pharmacies and distributors who are authorized to ship to certified outpatient pharmacies.

To become certified to dispense FILSPARI, outpatient pharmacies must:

1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.
2. Have the authorized representative review the ***Prescriber and Pharmacy Guide***.
3. Have the authorized representative certify by enrolling in the REMS by completing the ***Outpatient Pharmacy Enrollment Form*** and submitting it to the REMS:
   - **By fax**
4. Train all relevant staff involved in dispensing on REMS requirements using the ***Prescriber and Pharmacy Guide***.
5. Establish processes and procedures to verify the patient is enrolled and the prescriber is certified.
6. Establish processes and procedures to document and submit confirmation of counseling on the risks of hepatotoxicity and embryo-fetal toxicity.
7. 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.
8. For patients who can become pregnant: Establish processes and procedures to verify and document pregnancy testing is complete or the prescriber authorizes the refill.

To ensure compliance with FILSPARI REMS requirements, outpatient pharmacies must:

1. Before dispensing FILSPARI, the outpatient 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 processes and procedures established as a requirement of the REMS.
     - Counsel the patient on the risk of hepatotoxicity, the signs and symptoms of liver problems, the need to contact the prescriber if they have any signs or symptoms of liver problems, and the need to complete liver testing.
   - 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.
     - Counsel the patient on the risk of embryo-fetal toxicity, the need to use effective contraception during treatment and for one month following treatment discontinuation, the potential need for emergency contraception, the need to complete monthly pregnancy tests, and to inform the prescriber immediately if the patient misses a menstrual period or pregnancy is suspected.
   - **Verify** and document liver testing is complete or the prescriber authorizes the refill, and the patient's reproductive status has not changed through the processes and procedures established as a requirement of the REMS.
     - Confirm completion of liver testing monthly for the first 12 months, then every 3 months during treatment.
   - 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.
     - Confirm completion of pregnancy testing monthly and for one month following treatment discontinuation.
2. At all times, the outpatient pharmacy must:
   - **Dispense** no more than a 30-days' supply.
     - A certified prescriber may be eligible to provide the outpatient pharmacy a one-time authorization to dispense a greater than 30-days' supply. The outpatient pharmacy must report the reason to the FILSPARI REMS. For information on the eligibility to dispense more than a 30-days' supply and related authorization process, contact the FILSPARI REMS at 1-833-513-1325.
   - **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 data 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 being followed.
   - **Have a new authorized representative enroll by completing and submitting** an ***Outpatient Pharmacy Enrollment Form***, if the authorized representative changes.

Contact the FILSPARI REMS at 1-833-513-1325 for more information on becoming a certified outpatient pharmacy.

Login is available for certified pharmacies.

PDFs for Download

Resources for Outpatient Pharmacies

Prescriber and Pharmacy Guide

Outpatient Pharmacy Enrollment Form

Patient Guide

English
Spanish
Chinese

Inpatient Pharmacies

Only inpatient pharmacies within institutions such as hospitals, long-term care facilities, and prisons that are certified in the FILSPARI REMS may stock FILSPARI for patients being treated in the inpatient setting.

Contact the FILSPARI REMS to obtain contact information for certified inpatient pharmacies and distributors who are authorized to ship to certified inpatient pharmacies.

To become certified to dispense FILSPARI, inpatient pharmacies must:

1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.
2. Have the authorized representative review the ***Prescriber and Pharmacy Guide***.
3. Have the authorized representative certify by enrolling in the REMS by completing the ***Inpatient Pharmacy Enrollment Form*** and submitting it to the REMS:
   - **Online**
   - **By fax**
4. Train all relevant staff involved in dispensing on the REMS requirements using the ***Prescriber and Pharmacy Guide***.
5. 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.
6. For patients who can become pregnant: Establish processes and procedures to verify and document pregnancy testing is complete.

To ensure compliance with FILSPARI REMS requirements, inpatient pharmacies must:

1. Before dispensing FILSPARI, the inpatient pharmacy must:
   - **Counsel** the patient on the risk of hepatoxicity. Document and submit confirmation of counseling through the processes and procedures established as a requirement of the REMS.
     - Counsel the patient on the risk of hepatotoxicity, the signs and symptoms of liver problems, the need to contact the prescriber if they have any signs or symptoms of liver problems, and the need to complete liver testing.
   - 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.
     - Counsel the patient on the risk of embryo-fetal toxicity, the need to use effective contraception during treatment and for one month following treatment discontinuation, the potential need for emergency contraception, the need to complete monthly pregnancy tests, and to inform the prescriber immediately if the patient misses a menstrual period or pregnancy is suspected.
   - **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 by contacting the FILSPARI REMS **online** or by phone at 1-833-513-1325.
     - Liver testing will be required monthly for the first 12 months, then every 3 months during treatment.
   - For patients who can become pregnant: **Verify** and document pregnancy testing is complete.
     - Pregnancy testing will be required monthly and for one month following treatment discontinuation.
2. At discharge, the inpatient pharmacy must:
   - **Dispense** no more than a 30-days' supply.
3. At all times, the inpatient pharmacy must:
   - **Report** pregnancies to the REMS.
   - **Report** adverse events suggestive of hepatotoxicity to the REMS.
   - **Not** distribute, transfer, loan, or sell FILSPARI.
   - **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 being followed.
   - **Have a new authorized representative enroll by completing and submitting** an ***Inpatient Pharmacy Enrollment Form***, if the authorized representative changes.

Login is available for certified pharmacies.

PDFs for Download

Resources for Inpatient Pharmacies

Prescriber and Pharmacy Guide

Inpatient Pharmacy Enrollment Form

Patient Guide
English
Spanish
Chinese

FILSPARI™ REMS INPATIENT PHARMACY ENROLLMENT FORM

To become certified in the FILSPARI REMS, enroll by completing all fields below and submitting this form.

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 inpatient pharmacies that wish to stock FILSPARI must certify by enrolling in the FILSPARI REMS.

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 inpatient 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.

* *Indicates required field*

1 Inpatient Pharmacy Information

*Facility National Provider Identifier (NPI) #

CONTINUE

FILSPARI™ REMS INPATIENT PHARMACY ENROLLMENT FORM

To become certified in the FILSPARI REMS, enroll by completing all fields below and submitting this form.

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 inpatient pharmacies that wish to stock FILSPARI must certify by enrolling in the FILSPARI REMS.

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 inpatient 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.

* *Indicates required field*

1 Inpatient Pharmacy Information

*Facility National Provider Identifier (NPI) #

1234567890

*Inpatient Pharmacy Name

*Inpatient Pharmacy Location

○ Hospital ○ Nursing Home ○ Hospice ○ Mental Health Facility
○ Assisted Living ○ Prison ○ Rehabilitation Facility ○ Other (please specify)

Drug Enforcement Administration Number (DEA #)

Inpatient Pharmacy Address

*Address Line #1

Address Line #2

*City

*State

-- Please Select --

*Zip

*Phone

*Fax

Pharmacy Ship To Contact

*First Name

*Last Name

Pharmacy Shipping Address

☐ Pharmacy Shipping Address - Same as above

*Address Line #1

Address Line #2

*City

*State

-- Please Select --

*Zip

*Phone

*Fax

2 Inpatient Pharmacy Authorized Representative Information

*First Name

*Last Name

Position/Title:

○ Hospital pharmacist ○ Head of Pharmacy and Therapeutics (P&T) committee
○ Other (please specify)

*Authorized Representative Office Phone

*Fax

*Authorized Representative Email

*Contact Preference (select one):

○ Email ○ Fax

3 Inpatient 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 ***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.
- For patients who can become pregnant: Establish processes and procedures to verify and document pregnancy 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.
- 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 is enrolled or will be enrolled prior to discharge, the patient is under the care of a certified prescriber, and liver testing is complete.
- For patients who can become pregnant: Verify and document pregnancy testing is complete.

At discharge, my pharmacy must:

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

At all times, my pharmacy must:

- Report pregnancies to the REMS.
- Report adverse events suggestive of hepatotoxicity to the REMS.
- Not distribute, transfer, loan, or sell FILSPARI.
- 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 ***Inpatient Pharmacy Enrollment Form***, if the authorized representative changes.

4 Inpatient Pharmacy Authorized Representative Consent

By signing below, you agree that you have read the above responsibilities and understand your obligations as an inpatient 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

CLEAR | CANCEL | SUBMIT

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.

FILSPARI™ REMS INPATIENT PHARMACY ENROLLMENT FORM

To become certified in the FILSPARI REMS, enroll by completing all fields below and submitting this form.

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 inpatient pharmacies that wish to stock FILSPARI must certify by enrolling in the FILSPARI REMS.

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 inpatient 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.

* *Indicates required field*

1 Inpatient Pharmacy Information

*Facility National Provider Identifier (NPI) #

1234567890

*Inpatient Pharmacy Name

*Inpatient Pharmacy Location

○ Hospital ○ Nursing Home ○ Hospice ○ Mental Health Facility
○ Assisted Living ○ Prison ○ Rehabilitation Facility ◉ Other (please specify)

Drug Enforcement Administration Number (DEA #)

*Other Inpatient Pharmacy Location

Other

Inpatient Pharmacy Address

*Address Line #1

Address Line #2

*City

*State

-- Please Select --

*Zip

*Phone

*Fax

Pharmacy Ship To Contact

*First Name

*Last Name

Pharmacy Shipping Address

☑ Pharmacy Shipping Address - Same as above

2 Inpatient Pharmacy Authorized Representative Information

*First Name

*Last Name

Position/Title:

○ Hospital pharmacist ○ Head of Pharmacy and Therapeutics (P&T) committee
◉ Other (please specify)

*Other Position/Title

Please Specify

*Authorized Representative Office Phone

*Fax

*Authorized Representative Email

*Contact Preference (select one):

○ Email ○ Fax

3 Inpatient 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 ***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.
- For patients who can become pregnant: Establish processes and procedures to verify and document pregnancy 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.
- 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 is enrolled or will be enrolled prior to discharge, the patient is under the care of a certified prescriber, and liver testing is complete.
- For patients who can become pregnant: Verify and document pregnancy testing is complete.

At discharge, my pharmacy must:

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

At all times, my pharmacy must:

- Report pregnancies to the REMS.
- Report adverse events suggestive of hepatotoxicity to the REMS.
- Not distribute, transfer, loan, or sell FILSPARI.
- 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.
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☐ *Authorized Representative Signature

CLEAR | CANCEL | SUBMIT

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Inpatient Pharmacy Enrollment Submitted Successfully

Thank you for submitting your information to enroll in the FILSPARI REMS.

A confirmation of this submission has been sent to the email address provided. This email will also include instructions on how to create your web account for the FILSPARI REMS.

If you do not receive the email within the next few hours or would like to update your enrollment information at any time, please contact the FILSPARI REMS for assistance at 1-833-513-1325.

Resources

Resources for Prescribers

- *Prescriber and Pharmacy Guide*
- *Prescriber Enrollment Form*
- *Patient Enrollment Form*
  English
  Spanish
  Chinese
- *Patient Guide*
  English
  Spanish
  Chinese
- *Change in Reproductive Potential Status Form*

Resources for Patients

- *Patient Guide*
  English
  Spanish
  Chinese

Resources for Outpatient Pharmacies

- *Prescriber and Pharmacy Guide*
- *Outpatient Pharmacy Enrollment Form*
- *Patient Guide*
  English
  Spanish
  Chinese

Resources for Inpatient Pharmacies

- *Prescriber and Pharmacy Guide*
- *Inpatient Pharmacy Enrollment Form*
- *Patient Guide*
  English
  Spanish
  Chinese

Contact Us

Phone

1-833-513-1325

Fax

1-833-483-4736

Hours of Operation

Monday - Friday
8:00 AM - 8:00 PM
EST

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 FDA at 1-800-FDA-1088 or online at **www.fda.gov/medwatch**.

For FILSPARI REMS information contact:
Phone: 1-833-513-1325
Fax: 1-833-483-4736

Certified Outpatient Pharmacies

Below is a list of pharmacies certified in the FILSPARI REMS to dispense FILSPARI.

Download the list to spreadsheet format by clicking on the Excel icon just above the column headers

Search/Filter the list by entering information in the text box below any column header

Sort the list by clicking on any column header

Name	City	State	ZIP	Phone Number	Fax Number
ABC Pharmacy	Philadelphia	PA	12345	555-555-1212	555-555-2323