FILSPARI® REMS

PRESCRIBER AND PHARMACY GUIDE

FILSPARI®
(sparsentan) tablets
200 mg/400 mg

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FILSPARI REMS

INDICATION

FILSPARI is indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.

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 3.5% 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 then every 3 months during treatment with FILSPARI.

FILSPARI REMS OVERVIEW

Due to the risk of hepatotoxicity, 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 risk of hepatotoxicity associated with FILSPARI:

- Objective 1: Monitor for elevations in liver enzymes in patients exposed to 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
- Prescribers must educate and counsel patients on the risk of hepatotoxicity associated with FILSPARI using the **Patient Guide**
- Prescribers must assess liver function for patients prior to initiation of FILSPARI then every 3 months during treatment to receive FILSPARI
- Prescribers must report any adverse events suggestive of hepatotoxicity to the FILSPARI REMS

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 risk of hepatotoxicity associated with FILSPARI**
2. **Complete the Prescriber Enrollment Form**
   - Prescribers will attest to understanding the risk of hepatotoxicity associated with 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
     - 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. **Educate/counsel patients about the risk of hepatotoxicity associated with 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 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
5. **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

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 risk of hepatotoxicity
- Establish processes and procedures to verify and document the patient's liver 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

Before dispensing FILSPARI; at initial dispense, then every 3 months, the outpatient 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
- Verify and document the patient's liver testing is complete or the prescriber authorizes the refill through the processes and procedures established as a requirement of the REMS

At all times, the outpatient pharmacy must:

- Dispense no more than a 90-days' supply
  - A certified prescriber may be eligible to provide the outpatient pharmacy a one-time authorization to dispense a greater than 90-days' supply. The outpatient pharmacy must report the reason to the FILSPARI REMS. For information on the eligibility to dispense more than a 90-days' supply and related authorization process, contact the FILSPARI 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, except to certified dispensers
- 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

To maintain certification to dispense, the outpatient pharmacy must:

- 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

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
- 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 every 3 months during treatment

ROLE OF CERTIFIED PHARMACIES continued

At discharge, the inpatient pharmacy must:

- Dispense no more than a 30-days' supply

At all times, the inpatient pharmacy must:

- Report adverse events suggestive of hepatotoxicity to the REMS
- Not distribute, transfer, loan, or sell FILSPARI, except to certified dispensers
- Maintain records that all processes and procedures are in place and are being followed
- Comply with audits carried out by Travere Therapeutics, Inc. or a third party acting on behalf of Travere Therapeutics, Inc. to ensure that all processes and procedures are in place and are being followed

To maintain certification to dispense, the inpatient pharmacy must:

- 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**, and **Pharmacy Enrollment Forms (Outpatient and Inpatient)**
- Allows access to the FILSPARI REMS database to the certified pharmacies for verification of patient and prescriber information

Notes

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 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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