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, 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	✓	✓

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

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

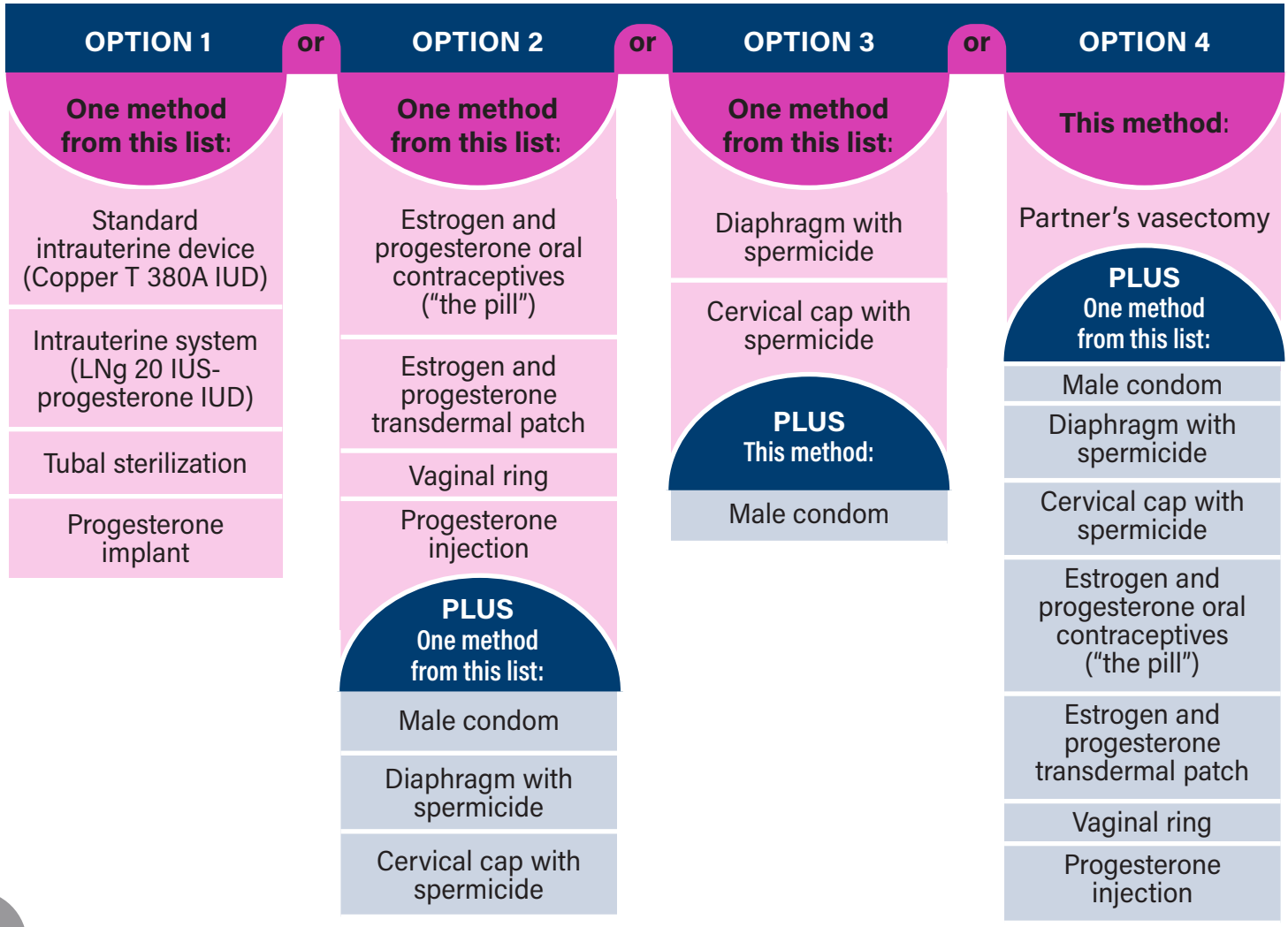
CONTRACEPTIVE OPTIONS FOR PATIENTS WHO CAN BECOME PREGNANT

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



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

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

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

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.

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