Ambrisentan REMS Outpatient Pharmacy Enrollment Form

To enroll in the Ambrisentan REMS, complete and fax this form to 1-866-750-9802

Due to the risk of embryo-fetal toxicity, ambrisentan is available only through a restricted program called the Ambrisentan REMS (Risk Evaluation and Mitigation Strategy). In order for patients to receive ambrisentan, all outpatient pharmacies that wish to stock this product, must enroll in the Ambrisentan REMS and agree to comply with the requirements of the program.

An Authorized Representative must be designated to carry out the certification process and oversee implementation of and compliance with the 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 REMS materials, please visit the REMS website at **www.ambrisentanrems.us.com**, or call the Ambrisentan REMS at **1-888-417-3172**.

Outpatient Pharmacy Information (PLEASE PRINT)

Pharmacy Name:

Identification (please complete one of the following):

☐ Facility Health Industry Number (HIN #): | ☐ Facility National Provider Identifier (NPI #): | ☐ Other identifier:

Address:

City: | State: | Zip:

Phone #: | Fax #:

Ship To Address (if different from above)

Address:

City: | State: | Zip:

Phone #: | Fax #:

Outpatient Pharmacy Authorized Representative Information (PLEASE PRINT)

Name: | Position/Title:

Credentials: ☐ RPh ☐ PharmD ☐ BCPS ☐ Other

Authorized Representative phone #: | Fax #:

Authorized Representative email:

Contact Preference (please select one) ☐ Email ☐ Fax

Outpatient Pharmacy Authorized Representative Responsibilities

I am the authorized representative designated by my pharmacy to coordinate the activities of the REMS. Therefore, I must:

- Carry out the certification process and oversee implementation of and compliance with the REMS on behalf of the pharmacy.
- Review the ***Prescriber and Pharmacy Guide***.
- Enroll in the REMS by completing and submitting the ***Outpatient Pharmacy Enrollment Form***.
- Train all relevant staff involved in dispensing ambrisentan on REMS procedures and materials using the ***Prescriber and Pharmacy Guide***.
- Ensure the pharmacy is able to support electronic data exchanges and communications with the Ambrisentan REMS.
- Establish processes and procedures to verify if the female patient is enrolled, the reproductive status of the patient has not changed, and the prescriber is certified.
- Establish processes and procedures to verify that pregnancy testing is complete or the prescriber authorizes the refill for females of reproductive potential.

On behalf of the pharmacy, I agree to comply with the following program requirements:

Prior to dispensing, the outpatient pharmacy must:

- Counsel females of reproductive potential on the risk of embryo-fetal toxicity, the need to use highly reliable contraception, emergency contraception, to get monthly pregnancy tests, and inform the prescriber of a pregnancy immediately.
- Verify the female patient is enrolled, the reproductive status has not changed, and the prescriber is certified through the processes and procedures established as a requirement of the REMS.
- For females of reproductive potential, verify that the pregnancy testing is complete or the prescriber authorizes the refill through the processes and procedures established as a requirement of the REMS.
- Dispense no more than a 30 days' supply for females of reproductive potential.

At all times, the outpatient pharmacy must:

- Report pregnancies to the REMS.
- Report a change or misclassification in reproductive status to the REMS.
- Not distribute, transfer, loan, or sell ambrisentan, except to certified dispensers.
- Maintain and submit records of daily product dispensing data for female patients of reproductive potential.
- Maintain records that all processes and procedures are in place and are being followed.
- Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and are being followed.

Outpatient Pharmacy Authorized Representative Consent

By signing below, you signify your understanding of the risks of ambrisentan treatment, your obligations as a pharmacy certified in the REMS as outlined above, and you agree to oversee the implementation of and compliance with the REMS requirements for this pharmacy.

Note: If your outpatient pharmacy needs ambrisentan and is not enrolled in the REMS, contact the Ambrisentan REMS at **1-888-417-3172** for assistance in initiating enrollment of the pharmacy.

Signature: | Date:

Please visit **www.ambrisentanrems.us.com** or call **1-888-417-3172** for more information about the Ambrisentan REMS Program.
This form is part of an FDA-approved REMS.