Ambrisentan REMS Inpatient Pharmacy Enrollment Form

To enroll in the Ambrisentan REMS, complete and fax this form to 1-866-750-9802 or complete and submit online at www.ambrisentanrems.us.com

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 inpatients to receive ambrisentan, all inpatient 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 inpatient 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**.

Inpatient Pharmacy Information (PLEASE PRINT)

Pharmacy Name:

☐ Hospital ☐ Nursing home ☐ Hospice ☐ Asylum/Mental facility ☐ Assisted Living ☐ Prison ☐ Rehabilitation

☐ Other (Please specify):

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 #:

Inpatient Pharmacy Authorized Representative Information (PLEASE PRINT)

Name: Position/Title: ☐ Hospital pharmacist ☐ Head of Pharmacy and Therapeutics (P&T) committee ☐ Other title:

Credentials: ☐ RPh ☐ PharmD ☐ BCPS ☐ Other

Authorized Representative phone #: Fax #:

Authorized Representative email:

Contact Preference (please select one) ☐ Email ☐ Fax

Inpatient 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 ***Inpatient Pharmacy Enrollment Form***.
- Train all relevant staff involved in dispensing ambrisentan on REMS procedures and materials using the ***Prescriber and Pharmacy Guide***.
- Establish processes and procedures to verify the female patient is enrolled or will be enrolled in the REMS prior to discharge, her reproductive status, and the female patient is under the supervision and care of a certified provider.
- For females of reproductive potential: establish processes and procedures to verify pregnancy testing is complete, and the patient is counseled on the risk of embryo-fetal toxicity, the need to use highly reliable contraception during treatment and for one month after stopping treatment, emergency contraception, to get monthly pregnancy tests, and to inform the prescriber of a pregnancy immediately.

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

Prior to dispensing, the inpatient pharmacy must:

- Verify the female patient is under the supervision and care of a certified prescriber, her reproductive status, and she is enrolled or will be enrolled in the REMS prior to discharge through the processes and procedures established as a requirement of the REMS.
- For females of reproductive potential: Verify that the pregnancy testing is complete, the patient is counseled on the risk of embryo-fetal toxicity, the need to use highly reliable contraception during treatment and for one month after stopping treatment, to get monthly pregnancy tests, and to inform the prescriber of a pregnancy immediately through the processes and procedures established as a requirement of the REMS.

At discharge of a patient, the inpatient pharmacy must:

- Dispense no more than a 15 days' supply.

At all times, the inpatient 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 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.

Inpatient 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 inpatient pharmacy needs ambrisentan and is not enrolled in the REMS, contact the 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.