

PS-Ambrisentan REMS Inpatient Pharmacy Enrollment and Agreement Form

An inpatient pharmacy is a pharmacy that dispenses prescriptions in an inpatient setting such as a hospital or a long-term care facility.

Due to the risk of embryo-fetal toxicity, ambrisentan is available only through a restricted program called the PS-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 PS-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.

To be enrolled into the PS-Ambrisentan REMS, complete and **fax this form to 1-888-870-1819**. Pharmacy enrollment may also be completed online at www.PSAmbrisentanREMS.com.

1 Inpatient Pharmacy Type (PLEASE SELECT ONE)

Hospital Nursing Home Hospice Asylum/Mental Facility Assisted Living Prison Rehabilitation Other

2 Inpatient Pharmacy Information (PLEASE PRINT)

Pharmacy Name:

Address:	City:	State:	Zip:
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Phone: ()	Fax: ()
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Organizational NPI #:	NCPDP #:	Pharmacy DEA #:
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3 Authorized Representative Information

Authorized Representative (First and Last Name):	Credentials: <input type="checkbox"/> RPh <input type="checkbox"/> PharmD <input type="checkbox"/> BCPS <input type="checkbox"/> Other
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Email Address:	Phone: ()
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Position/Title: <input type="checkbox"/> Hospital Pharmacist <input type="checkbox"/> Head of Pharmacy and Therapeutics (P&T) <input type="checkbox"/> Other	Preferred Method of Contact: <input type="checkbox"/> Phone Call <input type="checkbox"/> Email
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Inpatient Pharmacy Authorized Representative Responsibilities

I am the authorized representative designated by my pharmacy to coordinate the activities of the PS-Ambrisentan 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 **Pharmacy Guide**.
- Enroll in the REMS by completing and submitting the **Inpatient Pharmacy Enrollment Form**.
- Train all relevant staff involved in dispensing on REMS procedures and materials using the **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 prescriber.
- 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, 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 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 upon discharge.

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.

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

Required

Authorized Representative Signature:

X

Date:

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