

PS-Ambrisentan REMS Outpatient Pharmacy Enrollment and Agreement Form

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 patients to receive ambrisentan, all outpatient 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 outpatient 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 Outpatient Pharmacy Type (PLEASE SELECT ONE)			
<input type="checkbox"/> Central Fill	A central fill pharmacy is a pharmacy that fills prescriptions on behalf of an originating pharmacy with which it has a contractual agreement to provide such services or with which it shares a common owner. A central fill pharmacy must ensure that the originating pharmacies do not stock ambrisentan.		
<input type="checkbox"/> Specialty	Specialty pharmacy is defined as the service created to manage the handling and service requirements of specialty pharmaceuticals, including dispensing, distribution, reimbursement, case management, and other services specific to patients with rare and/or chronic diseases.		
<input type="checkbox"/> Just-in-Time	Pharmacies that do not use a central fill pharmacy may still certify and enroll in the PS-Ambrisentan REMS. To do so, these pharmacies must agree to not stock ambrisentan and to only order ambrisentan on a just-in-time , per patient per prescription basis.		
2 Outpatient Pharmacy Information (PLEASE PRINT)			
Pharmacy Name:		Phone: ()	Fax: ()
Address:		City:	State: Zip:
Organizational NPI #:	NCPDP #:	Pharmacy DEA #:	
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	Position/Title:
Email Address:		Phone: ()	Preferred Method of Contact: <input type="checkbox"/> Phone Call <input type="checkbox"/> Email

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4 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 **Outpatient Pharmacy Enrollment Form**
- Train all relevant staff involved in dispensing ambrisentan on the REMS requirements using the **Pharmacy Guide**.
- Establish processes and procedures to verify if the female of reproductive potential is counseled and the authorization number is valid.

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

Prior to dispensing, the outpatient pharmacy must:

- Validate or obtain a REMS Dispense Authorization (RDA) from the REMS Coordinating Center or REMS website that verifies female patients are enrolled, the reproductive status has not changed, the prescriber is certified, and pregnancy test is completed for females of reproductive potential or the prescriber authorizes the refill through the processes and procedures established as a requirement of the REMS.
- Not fill the prescription if an RDA cannot be obtained or verified. Must instruct patient to call the REMS Coordinating Center to provide the missing information.
- Record the NDC number and days' supply of the dispensed drug with the REMS once an RDA is validated or obtained.
- For females of reproductive potential: Verify that the patient is counseled through the processes and procedures established as a requirement of the REMS. If monthly counseling has not been completed when an RDA is issued, the RDA will contain counseling guidelines and a message indicating to counsel the patient, OR call the REMS Coordinating Center to receive counseling guidelines and then counsel the patient, OR instruct the patient to call the REMS Coordinating Center to receive counseling.
- For Females of Reproductive Potential: Dispense no more than a 30 days' supply.

Prior to dispensing, the Originating Outpatient Pharmacy using Central Fill Pharmacy must:

- Not stock ambrisentan
- Fill all ambrisentan prescriptions through an associated central fill pharmacy certified in the REMS.

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.
- For pharmacies authorized to receive bulk shipments: Maintain and submit records of daily product dispensing data.
- 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.

Additionally, at all times, the Outpatient Pharmacy Ordering on a Per Patient Per Prescription must:

- Not stock ambrisentan
- Order ambrisentan just-in-time on a per patient per prescription basis from a wholesaler-distributor registered in the REMS and provide with the order an indication that the patient is male or the RDA for a female patient.
- Order and dispense no more than a 30-day supply to Females of Reproductive Potential

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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