What is the PS-Ambrisentan Risk Evaluation and Mitigation Strategy (REMS)?

The PS-Ambrisentan Risk Evaluation and Mitigation Strategy (REMS) Program

A Risk Evaluation and Mitigation Strategy is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

The PS-Ambrisentan REMS is a safety program that manages the risk of serious birth defects when taking ambrisentan. The PS-Ambrisentan REMS is required by the Food and Drug Administration (FDA).

- Only prescribers and pharmacies certified by the PS-Ambrisentan REMS can prescribe and dispense ambrisentan to patients
- Patients must be enrolled in the PS-Ambrisentan REMS and follow all the safety rules in the REMS in order to receive ambrisentan.
What is the PS-Ambrisentan Risk Evaluation and Mitigation Strategy (REMS)?

The PS-Ambrisentan Risk Evaluation and Mitigation Strategy (REMS) Program

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<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Company</th>
<th>Telephone</th>
<th>NDC Code</th>
</tr>
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<tbody>
<tr>
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<td>Test Co AAA</td>
<td>111-111-1111</td>
<td>1111-1111-11 - Name 1 Capsules nmg Total 30</td>
</tr>
<tr>
<td>SomeMolecule</td>
<td>Test Co AAA</td>
<td>111-111-1111</td>
<td>1111-1112-12 - Name 2 Capsules nmg Total 60</td>
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<td>Test Co BB</td>
<td>222-222-2222</td>
<td>2222-2222-11 - Name 3 Capsules nmg Total 60</td>
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<tr>
<td>SomeMolecule</td>
<td>Test Co BB</td>
<td>222-222-2222</td>
<td>2222-2223-12 - Name 4 Capsules nmg Total 120</td>
</tr>
<tr>
<td>Pharmacy Name</td>
<td>Phone Numbers</td>
<td>Website Links</td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>------------------------</td>
<td>-----------------------------</td>
<td></td>
</tr>
<tr>
<td>A PHARMACY, L.L.C.</td>
<td>401-555-1500&lt;br&gt;800-555-8452&lt;br&gt;www.APPharmacy.com</td>
<td></td>
<td></td>
</tr>
<tr>
<td>JOHN RX, LLC</td>
<td>215-555-1060&lt;br&gt;866-555-2170&lt;br&gt;www.JohnRX.com</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DISCOUNT DRUG INC</td>
<td>717-555-2633&lt;br&gt;717-555-8659&lt;br&gt;www.DiscountDrugs.com</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ARWENS INC</td>
<td>215-555-6337&lt;br&gt;215-555-0355&lt;br&gt;www.arwens.com</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
General FAQs

- What does PS mean?
- What type of information is collected by the PS-Ambrisentan REMS and who will see it?
- Why aren’t I receiving emails from the PS-Ambrisentan REMS?
- How do I download the PS-Ambrisentan REMS app on my mobile device?
- What if I need help using the website?
- What browser types and versions does the PS-Ambrisentan REMS website support?
- How does the PS-Ambrisentan REMS website use cookies?
- What do I do if I can’t view a document on the website?
- How do I report a problem with the PS-Ambrisentan REMS website?
- How do I obtain a username and password for the PS-Ambrisentan REMS website?
- What if I do not receive the verification email after I created my account?
- What do I do if I forgot my password?
- What do I do if I forgot my username?
- What do I do if my user account is locked?
- How do I change my username and/or password?
- What is two-factor authentication (2FA)?

Prescriber FAQs

- How do patients enroll in the PS-Ambrisentan REMS?
- How do prescribers enroll in the PS-Ambrisentan REMS?
- What are the PS-Ambrisentan REMS requirements for prescribers?
- How do I find a pharmacy to fill an ambisentan prescription for patients?
- Do prescribers need to enroll in the PS-Ambrisentan REMS if already enrolled in the Letairis REMS?
- Do healthcare providers who prescribe ambisentan have to enroll in the PS-Ambrisentan REMS?
- What if a patient gets pregnant during treatment with ambisentan or within one month of discontinuation of treatment?
- Does the PS-Ambrisentan REMS have a mobile app?

Pharmacy FAQs

- How does a patient enroll in the PS-Ambrisentan REMS?
- How does a pharmacy enroll in the PS-Ambrisentan REMS?
- What are the PS-Ambrisentan REMS requirements for pharmacies?
- What are the pharmacy types for which a pharmacy can be classified?
- How does a pharmacy validate or obtain a REMS Dispense Authorization (RDA)?
- Does a pharmacy need to enroll in the PS-Ambrisentan REMS if already enrolled in the Letairis REMS?
- Can a chain pharmacy create an account to enroll and manage multiple pharmacies?

Patient FAQs

- What is ambisentan?
- What are the serious risks of ambisentan?
- What is the PS-Ambrisentan Risk Evaluation and Mitigation Strategy (REMS)?
- Is this REMS mandatory?
- What are the PS-Ambrisentan REMS requirements for female patients?
- How do I enroll in the PS-Ambrisentan REMS?
- Can I be pre-enrolled in the PS-Ambrisentan REMS?
- Do patients need to enroll in the PS-Ambrisentan REMS if already enrolled in the Letairis REMS?
- Do male patients taking ambisentan need to enroll?
- What are birth control options for female patients taking ambisentan?
- How will I receive my ambisentan?
- What is an RDA?
- What should a patient do if she gets pregnant while taking ambisentan?
- If a patient is unable to get pregnant, does she still need to enroll?
- Where can the medication guide be found for this product?
- Where can patients fill ambisentan prescriptions?
- What does it mean to transfer doctors?
- If I transfer doctors, will my previous doctor still be able to see my information in the PS-Ambrisentan REMS system?
- Will a transfer cause an interruption in my treatment?
- How does a transfer work?
Contact Us

8:00 AM to 4:00 PM
Monday - Friday

(888) 301-0333

(888) 870-1819

Download the REMS patient or prescriber app!

Available on the
App Store

Available on the
Google Play

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Patient

- What is ambrisentan?
  Ambrisentan is a prescription medicine used to treat pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs. Ambrisentan can improve your ability to exercise and it can help slow down the worsening of your physical condition and symptoms.
  It is not known if ambrisentan is safe and effective in children.

- What are the serious risks of ambrisentan?
  Ambrisentan can cause serious birth defects if taken during pregnancy. Females must not be pregnant when they start taking ambrisentan or become pregnant while taking ambrisentan, or for one month after stopping ambrisentan.

- What is the PS-Ambrisentan Risk Evaluation and Mitigation Strategy (REMS)?

- Is this REMS mandatory?

Find A Pharmacy

Find a pharmacy participating in the PS-Ambrisentan REMS.

Pre-Enroll

A tool to help the female ambrisentan patient start the enrollment process. The enrollment will be completed by the patient’s doctor.
Patient Pre-Enrollment

Instructions

All female patients taking ambrisentan must be enrolled in the PS-Ambrisentan REMS. A doctor enrolled in the PS-Ambrisentan REMS must complete the enrollment, but the patient may start the enrollment with the Patient Pre-Enrollment process. This will save the patient and the doctor time in completing the enrollment process.

1. **Patient Information** - When pre-enrolling, the patient will enter information such as name, address, phone number, date of birth, and email address.

2. **Alternate Contact** - The patient may enter information about another person the REMS Coordinating Center can contact if the patient cannot be reached. Parent/Guardian contact information is required for a patient that is under the age of 18 years old.

3. **Account Setup** - Create a username and password for your program account

4. **Agreement** - You must agree to understanding the PS-Ambrisentan REMS requirements for female patients and sign or enter your name.

5. **Complete Pre-Enrollment** - When the Pre-Enrollment is complete, a "Pre-Enrollment Confirmation Number" will be presented that can be provided to an PS-Ambrisentan REMS enrolled doctor to complete the enrollment.
## Patient Pre-Enrollment

### Patient

<table>
<thead>
<tr>
<th>Name</th>
<th>M. I.</th>
<th>Email</th>
<th>Address</th>
<th>Mobile Phone</th>
<th>Home Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jane Smith</td>
<td>Q</td>
<td><a href="mailto:testaccount2@examoto.com">testaccount2@examoto.com</a></td>
<td>100 Main Street</td>
<td>(610) 800-9000</td>
<td>(610) 500-6000</td>
</tr>
<tr>
<td></td>
<td></td>
<td><a href="mailto:testaccount2@examoto.com">testaccount2@examoto.com</a></td>
<td>Address Line 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>New York</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Date of Birth: 10/20/1990

### Gender: Female
Alternate Contact

Name
John
Smith

Email
testaccount2@examoto.com
testaccount2@examoto.com

Phone
(610) 600-7000

If necessary, how should we contact him/her?
- Email
- Phone Call

In general, what is the best time to contact him/her?
- Morning
- Afternoon
- Evening
Parent/Guardian Name
John
Smith

Required Parent or Guardian Alternate Contact

⚠️ The enrolling patient is a minor. A parent or guardian will need to complete this page.

Parent/Guardian Name
John
Smith

Email
testaccount5@examoto.com
testaccount5@examoto.com

Phone
(610) 600-7000

If necessary, how should we contact him/her?
- Email
- Phone Call

In general, what is the best time to contact him/her?
- Morning
- Afternoon
- Evening

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Account Setup

Enter your username

janesmith

Please create your password

************

************

Two-Factor Authentication Enabled

Two-Factor Authentication
Two-factor authentication (2FA) adds a second level of authentication to an account login. In addition to something the user knows, such as a username and password, a user is required to supply something they have. With 2FA disabled, the user is required to provide their username and password. With 2FA enabled, the user is required to additionally enter a unique code that is provided through an SMS text, an email, or an authenticator app. 2FA is configured to use email by default. This can be changed via Preferences after account creation.

NEXT ➔
For Females Who Can Get Pregnant:
Before I begin ambrisentan treatment, I will:

- Review the Guide for Female Patients.
- Get a pregnancy test.
- Enroll in the REMS by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS.
- Receive counseling from the prescriber on the risk of serious birth defects, the need to use highly reliable contraception during treatment and for one month after stopping treatment, and emergency contraception using the Guide for Female Patients.

Before I receive each prescription of ambrisentan, I will:

- Receive counseling from the prescriber or REMS Coordinating Center on risk of serious birth defects, 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 report a pregnancy immediately.
- Get a pregnancy test.
- Communicate with the REMS Coordinating Center to confirm pregnancy testing.

During my treatment with ambrisentan and for one month after stopping treatment, I will use highly reliable contraception as described in the Guide for Female Patients.

I will get a pregnancy test one month after I stop taking ambrisentan.

I agree to be contacted by the REMS to obtain information about my pregnancy if I become pregnant while on ambrisentan or within 30 days after stopping treatment.

For Pre-Pubertal Females (and their guardians):
Before I begin ambrisentan treatment, I will:

- Review the Guide for Female Patients.
- Enroll in the REMS by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS.
- Receive counseling from the prescriber on the risk of serious birth defects using the Guide for Female Patients.

If I am over the age of 8 and while I am being treated with ambrisentan, I will be monitored regularly for a change in reproductive status.

I will tell my prescriber if my reproductive status (ability to become pregnant) changes.

For Post-menopausal Females or Females with other medical reasons for permanent, irreversible infertility:
Before I begin ambrisentan treatment, I will:

- Review the Guide for Female Patients.
- Enroll in the REMS by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS.

I will tell my prescriber if my reproductive status (ability to become pregnant) changes.

Patient or Parent/Guardian of patients under the age of 18 must sign below.

I understand the PS-Ambrisentan REMS requirements for a female patient

Patient or Parent/Guardian Signature:

Please use your stylus or mouse to sign your name, Jane Q Smith, in the box below:

[Signature]

AGREEMENT
Complete Pre-Enrollment

You have successfully completed the Patient Pre-Enrollment.

“Patient Pre-Enrollment Confirmation Number”

1dc23040

Please provide this Confirmation Number to your doctor. For your convenience we can email or text you the Confirmation Number.

- Email the Confirmation Number to testaccount2@examoto.com
- Text the Confirmation Number to (610) 800-9000
Mobile App
The mobile app is available for iOS and Android and contains similar patient functionality to the REMS web site.

Confirm Pregnancy Test
Confirm your monthly pregnancy test.

View RDA
View your current REMS Dispense Authorization

My Doctor
Your doctor's contact information
DR. Test Prescriber D.O.
5401 RAINBOW BLVD # MS 7007
PULMONARY FELLOWSHIP
KANSAS CITY, IA
66160-8500
555-555-6046
Monthly Pregnancy Test

- Monthly Pregnancy Test Obtained

Information

Confirm that you have had a pregnancy test within the last month.
REMS Dispense Authorization (RDA) Verified

b98a101b

⚠️ RDA expires at midnight on 4/3/2019

Email the RDA to testaccount1@examoto.com

Text the RDA to (610) 444-5555
Jenn A Patient
Username: JennJD

My Doctor

DR. Test Prescriber D.O.
5401 RAINBOW BLVD # MS 7007
PULMONARY FELLOWSHIP
KANSAS CITY, IA 66160-8500
555-555-6046

Patient Events

Filter Events by: All

- Invited To Enroll: 3/4/2019 UTC
- Pre-Enrolled: 3/4/2019 UTC
- Enrollment: 3/4/2019 UTC
- Diagnostic Entry: 3/4/2019 UTC
- RDA Created: 3/4/2019 UTC
- Reproductive Potential Status: 3/4/2019 UTC
- Diagnostic Entry: 3/4/2019 UTC
- Attestment: 3/4/2019 UTC

Information

This is the contact information for your current doctor. You may initiate a transfer to another doctor by selecting the Transfer Doctor button.
Transfer Doctor

What does it mean to transfer doctors?
Transferring to another doctor means your current doctor will no longer be able to see any of your information in the PS-Ambrisantan REMS and the PS-Ambrisantan REMS will no longer provide information about you to your current doctor. To continue ambrisantan treatment, you will need to find another doctor enrolled in the PS-Ambrisantan REMS. You can choose to transfer back to this doctor at any time.

Will my current doctor still be able to see my information in the system?
Once you complete the transfer request below, your current doctor will no longer be able to see any of your information in the PS-Ambrisantan REMS. Your current doctor may still have access to his or her own copies of your medical information.

Will this cause an interruption in my treatment?
This depends on when you received your last prescription and how quickly you can begin treatment with a new doctor. You should talk to your doctor to ensure that an interruption in treatment does not occur.

How does the process work?
You will receive a Transfer Doctor Confirmation Number. You will need to provide this Confirmation Number to your new doctor. The doctor will use this Confirmation Number to register you under their care in the PS-Ambrisantan REMS. Once this is complete, your treatment will continue with the new doctor.

Transfer Doctor

☐ I want to transfer my ambrisantan treatment to another doctor.
You have successfully started the transfer to another doctor.

Transfer Doctor Confirmation Number

d53e471c

Please provide this Confirmation Number to your new doctor to complete your transfer. For your convenience we can email or text you the Confirmation Number.

- Email the Confirmation Number to testaccount1@examoto.com
- Text the Confirmation Number to (610) 444-5555
Prescriber

How do patients enroll in the PS-Ambrisentan REMS?
Upon receipt of a completed Patient Enrollment Form, a REMS Coordinating Center Associate will ensure that the prescriber submitting the Patient Enrollment Form is enrolled in the REMS. Upon confirmation of an enrolled prescriber, the associate will enter the information into the REMS system completing the patient’s enrollment and linking the enrolled patient with the enrolled prescriber. An enrolled prescriber may also enroll female patients through the REMS website or mobile app. Both the prescriber and patient (or parent/guardian for minors) must sign the form.

How do prescribers enroll in the PS-Ambrisentan REMS?
To become certified, a prescriber must complete and submit the Prescriber Enrollment and Agreement Form. The form may be completed and submitted online via the REMS website, through the REMS mobile app, or by printing and faxing a completed form to the REMS Coordinating Center.

What are the PS-Ambrisentan REMS requirements for prescribers?
Prescribers must enroll in the PS-Ambrisentan REMS and comply with the PS-Ambrisentan REMS requirements to prescribe ambrisentan, even if previously enrolled in the Letairis REMS.

Materials for Prescribers

- Prescriber Enrollment and Agreement Form
- Prescriber Guide
- Patient Enrollment and Consent Form
- Guide for Female Patients
- Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form
- Prescriber FAQs
Prescriber Enrollment

Instructions

Healthcare providers who prescribe ambrisentan (prescribers) must be specially certified and enrolled in the PS-Ambrisentan REMS (even if previously enrolled in the Letairis REMS). To become certified, the prescriber must first read the Prescribing Information and the Prescriber Guide, and then agree to follow the PS-Ambrisentan REMS requirements by completing the Prescriber Enrollment and Agreement Form.

Overview of online enrollment:

1. **Prescriber Information** - Prescribers will enter an individual National Provider Identifier (NPI) number. This will be used to obtain most of the information needed for enrollment. The prescriber will be asked to provide additional information about the best time and way to be contacted.

2. **Office Information** - The prescriber will be asked to provide information for an additional person in the office that may be contacted.

3. **Create Password** - The prescriber will be asked to enter a password to create the program account. Upon creation of the account, the prescriber will receive an email with a link. Upon clicking on the link in the email, the prescriber will be asked to log in and complete the enrollment.

4. **Agreement** - The prescriber will be asked to provide their signature. By signing, the prescriber signifies their understanding of the risks associated with ambrisentan treatment and their obligation as an ambrisentan prescriber to educate female patients about these risks, counsel them on risk reduction, monitor them appropriately, and report adverse events to the REMS Coordinating Center.

5. **Complete** - The enrollment will be completed upon agreeing and providing a signature.
Prescriber Enrollment

Prescriber Information

Please provide an individual NPI number

Enter NPI number

FIND

NPI Information

GARY DOE DO

Mailing Address
1111 LION ROAD
SomeWhere, PA 11111

Taxonomies (★ - Primary)
★ 1111111111X - Internal Medicine Pulmonary Disease

Email

testaccount5@examoto.com

testaccount5@examoto.com

Mobile Phone

(610) 800-9000

If necessary, how should we contact you?

Email  Text To Mobile  Phone Call

In general, what is the best time to contact you?

Morning  Afternoon  Evening
Agreement

Please read and accept the following terms:

By signing below, you attest to the following:
I have reviewed the Prescribing Information and Prescriber Guide and agree to comply with the PS-Ambrisentan REMS requirements.

For all females:
• I will determine the reproductive potential status of all female patients using the definitions provided in the Prescriber Guide and document and submit the results to the REMS using the Patient Enrollment Form.
• I will counsel all female patients that ambrisentan is only available through a restricted distribution program called the PS-Ambrisentan REMS.
• I will enroll all female patients by completing and submitting the Patient Enrollment Form.

For females of reproductive potential:
• I will counsel Females of Reproductive Potential about the risk of embryo-fetal toxicity, the need to use highly reliable contraception during treatment and for one month following treatment discontinuation, and emergency contraception using the Guide for Female Patients.
• I will assess the pregnancy status of Females of Reproductive Potential by ordering and reviewing a pregnancy test before treatment initiation, before writing each prescription, and for one month after treatment discontinuation.
• I will counsel Females of Reproductive Potential if they are not complying with the required testing or if they are not using appropriate contraception.

For pre-pubertal females:
• I will counsel each Pre-Pubertal Female patient and her parent/guardian about the risk of embryo-fetal toxicity using the Guide for Female Patients.
• I will regularly assess the reproductive status of each Pre-Pubertal Female during their treatment with ambrisentan.
• I will document and submit findings to the REMS at least annually using the Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form.

At all times:
• I will report a change or misclassification in reproductive status to the REMS using the Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form within 10 business days of becoming aware of the change in reproductive status.
• I will report pregnancies to the REMS.

☑️ I understand and agree to all the terms above

SIGN

Prescriber Signature:

Please use your stylus or mouse to sign your name, GARY DOE, in the box below:

AGREEMENT
GARY DOE DO
NPE: 1000000099

Prescriber Enrollment

Complete

GARY DOE DO, your enrollment in the PS-Ambrisantan REMS is complete.

You may choose from the following options or navigate to your desired function utilizing the prescriber menu at the top of the page.

- Manage Patients
  - Manage your enrolled patients
  - Invite new patients to pre-enroll
  - Change patient's reproductive status
  - Manage your office staff

- Mobile App
  - The mobile app is available for iOS and Android and contains similar prescriber functionality to the REMS web site.

- Preferences
  - Update your personal preferences.

- Print enrollment form
  - Print or download a PDF copy of your completed enrollment form.

Manage Patients

Mobile App

Preferences

Print enrollment form

Available on the
App Store

Available on the
Google Play
<table>
<thead>
<tr>
<th>Classification</th>
<th>Name</th>
<th>Status</th>
<th>Date of Birth</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female of Reproductive Potential</td>
<td>Test A Patient</td>
<td>Enrolled as of</td>
<td>8/13/1978</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3/4/2019</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Key:** 🔴 Monthly Pregnancy Test 🔺 View RDA 🔹 Reproductive Status 🔴 Disenroll Patient 🔴 Re-Enroll Patient 🔴 Patient Detail

**Program Status:** Enrolled as of 3/4/2019

**New Patient Actions**
- 🔴 SEND PATIENT AN INVITATION TO PRE-ENROLL
- 🔺 COMPLETE A PATIENT ENROLLMENT USING A PRE-ENROLL CODE
- 🔴 ENROLL A PATIENT

**Existing Patient Actions**
- 🔴 ACCEPT TRANSFERRING PATIENT

**Materials for Prescribers**

- Prescriber Enrollment and Agreement Form
- Prescriber Guide
- Patient Enrollment and Consent Form
- Guide for Female Patients
- Change in Reproductive Potential Status and Pre-Pubertal Annual Verification From
- Prescriber FAQs
Send Patient an Invitation to Pre-Enroll

Patient Name
Betty
Parker

Patient Email
- testaccount4@examoto.com
- testaccount4@examoto.com

HIPAA Acknowledgement
I understand this email may contain Personally Identifiable Information and that I have the appropriate HIPAA agreements in place with this patient.

Information
This allows a prescriber to send an email to a patient inviting the patient to pre-enroll in the program. The email will contain a link for the patient to pre-enroll in the program. This allows the patient to enter demographic and other program related information prior to the office visit. The patient pre-enrollment process will result in a unique Pre-Enrollment Confirmation Number. When entered by the prescriber, this Confirmation Number will prepopulate the patient enrollment data and expedite the enrollment of the patient by the prescriber.

CANCEL  SEND PATIENT AN INVITATION TO PRE-ENROLL
Complete A Patient Enrollment using a Pre-Enroll Code

Please enter the Patient Pre-Enrollment Confirmation Number provided by the patient:

94482f42

LOOKUP

*Patient Pre-Enrollment Confirmation Number*

A "Patient Pre-Enrollment Confirmation Number" was provided to the patient upon completion of the Patient Pre-Enrollment. If a Patient Pre-Enrollment was not completed, the patient must be enrolled using the Start Patient Enrollment button.

Information

To complete a patient enrollment:

1. Enter the patient's Pre-Enrollment Confirmation Number.
2. Verify the correct patient information is displayed.
3. Select the patient's current reproductive status.
4. For a female of reproductive potential, indicate that a negative pregnancy test has been confirmed.
5. Certify that for female patients, you have provided the appropriate counseling and PS-Ambrisentan REMS materials and will continue to fulfill the required obligations under the PS-Ambrisentan REMS Program.
Instructions

All female patients taking ambrisentan must be enrolled in the PS-Ambrisentan REMS.

1. **Patient Information** - Enter information about the patient such as name, address, phone number, date of birth, and email address.

2. **Alternate Contact** - The patient may enter information about another person the REMS Coordinating Center can contact if the patient cannot be reached. Parent/Guardian contact information is required for a patient that is under the age of 18 years old.

3. **Reproductive Potential Status** - Enter the reproductive potential status of the patient. For a female of reproductive potential, indicate that a negative pregnancy test has been confirmed. Certify that for female patients, you have provided the appropriate counseling and PS-Ambrisentan REMS materials and will continue to fulfill the required obligations under the PS-Ambrisentan REMS.
Complete A Patient Enrollment using a Pre-Enroll Code

Please enter the Patient Pre-Enrollment Confirmation Number provided by the patient

![Enter Confirmation Number](LOOKUP)

Patient Information
Name: Jane Q Smith
Date of Birth: 10/20/1990 12:00:00 AM

Select the patient’s diagnosis below

**Diagnosis: Pulmonary Arterial Hypertension** (the following is not to suggest approved uses or indications. Please select one category below.)

- [ ] Primary Pulmonary Hypertension
- [ ] Pulmonary Hypertension, Secondary
- [ ] Pulmonary Heart Disease, unspecified
- [ ] Other

Select the female patient’s current reproductive status below

**Females of Reproductive Potential:**

- [ ] Female of Reproductive Potential - includes girls who have entered puberty and all women who have a uterus and have not passed through menopause.
  - Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or postsurgical from bilateral oophorectomy. For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal).

**Females of Non-Reproductive Potential:**

- [ ] Pre-pubertal Female - includes females who are at Tanner Stage 1 and 2.
- [ ] Post-menopausal Female - females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or postsurgical from bilateral oophorectomy.
- [ ] Other medical reasons for permanent, irreversible infertility

**Pregnancy Test**
A negative pregnancy test has been confirmed prior to prescribing ambrisentan

- [ ] Yes
- [ ] No

**Prescriber Obligations Under the PS-Ambrisentan REMS**

For All Females
- I will determine the reproductive potential status of all female patients using the definitions provided in the Prescriber Guide and document and submit the results to the REMS using the Patient Enrollment Form.
- I will counsel all female patients that ambrisentan is only available through a restricted distribution program called the PS-Ambrisentan REMS.
- I will enroll all female patients by completing and submitting the Patient Enrollment Form.

For Females of Reproductive Potential
- I will counsel Females of Reproductive Potential about the risk of embryo-fetal toxicity, the need to use highly reliable contraception during treatment and for one month following treatment discontinuation, and emergency contraception using the Guide for Female Patients.
- I will assess the pregnancy status of Females of Reproductive Potential by ordering and reviewing a pregnancy test before treatment initiation, before writing each prescription, and for one month after treatment discontinuation.
- I will counsel Females of Reproductive Potential if they are not complying with the required testing or if they are not using appropriate contraception.

For Pre-Pubertal Females
- I will counsel each Pre-Pubertal Female patient and her parent/guardian about the risk of embryo-fetal toxicity using the Guide for Female Patients.
- I will regularly assess the reproductive status of each Pre-Pubertal Female during their treatment with ambrisentan.
- I will assess the reproductive status for Pre-Pubertal Females who are 8 years of age and older and will document and submit findings to the REMS at least annually using the Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form.

**Certification**

I certify that for female patients, I have provided the appropriate counseling and PS-Ambrisentan REMS materials, and I will continue to fulfill my obligations under the PS-Ambrisentan REMS as outlined above.
Accept Transferring Patient

Please enter the Transfer Confirmation Number provided by the patient

<\/> abd0a111  LOOKUP  i

Information

To accept a patient transfer:
1. Enter the patient's Transfer Confirmation Number
2. Verify the correct patient information is displayed
3. Select the patient's current reproductive status
4. For a female of reproductive potential, indicate that a negative pregnancy test has been confirmed
5. Certify that for female patients, you have provided the appropriate counseling and PS-Ambrisentan REMS materials and will continue to fulfill the required obligations under the PS-Ambrisentan REMS
6. The patient will receive an email notification that the transfer has been accepted.
Accept Transferring Patient

Please enter the Transfer Confirmation Number provided by the patient

abd0a111

LOOKUP

Patient Information

Name: Jenn A Patient
Date of Birth: 6/13/1970

Please note that the last pregnancy test for this patient was on 3/4/2019.

Select the patient’s diagnosis below

Diagnosis: Pulmonary Arterial Hypertension (the following is not to suggest approved uses or indications. Please select one category below.)

- Primary Pulmonary Hypertension
- Pulmonary Hypertension, Secondary
- Pulmonary Heart Disease, unspecified
- Other

Select the female patient’s current reproductive status below

Females of Reproductive Potential:

- Female of Reproductive Potential - includes girls who have entered puberty and all women who have a uterus and have not passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or postsurgical from bilateral oophorectomy. For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menaestis (premenarchal).

Females of Non-Reproductive Potential:

- Pre-pubertal Female - includes females who are at Tanner Stages 1 and 2.
- Post-menopausal Female - females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or postsurgical from bilateral oophorectomy.
- Other medical reasons for permanent, irreversible infertility

Pregnancy Test

A negative pregnancy test has been confirmed prior to prescribing ambrisentan

- Yes
- No

Prescriber Obligations Under the PS-Ambrisentan REMS

For All Females

- I will determine the reproductive potential status of all female patients using the definitions provided in the Prescriber Guide and document and submit the results to the REMS using the Patient Enrollment Form.
- I will counsel all female patients that ambrisentan is only available through a restricted distribution program called the PS-Ambrisentan REMS.
- I will enroll all female patients by completing and submitting the Patient Enrollment Form.

For Females of Reproductive Potential

- I will counsel Females of Reproductive Potential about the risk of embryo-fetal toxicity, the need to use highly reliable contraception during treatment and for one month following treatment discontinuation, and emergency contraception using the Guide for Female Patients.
- I will assess the pregnancy status of Females of Reproductive Potential by ordering and reviewing a pregnancy test before treatment initiation, before writing each prescription, and for one month after treatment discontinuation.
- I will counsel Females of Reproductive Potential if they are not complying with the required testing or if they are not using appropriate contraception.

For Pre-Pubertal Females

- I will counsel each Pre-Pubertal Female patient and her parent/guardian about the risk of embryo-fetal toxicity using the Guide for Female Patients.
- I will regularly assess the reproductive status of each Pre-Pubertal Female during their treatment with ambrisentan.
- I will assess the reproductive status for Pre-Pubertal Females who are 8 years of age and older and will document and submit findings to the REMS at least annually using the Change In Reproductive Potential Status and Pre-Pubertal Annual Verification Form.

Certification

I certify that for female patients, I have provided the appropriate counseling and PS-Ambrisentan REMS materials, and I will continue to fulfill my obligations under the PS-Ambrisentan REMS as outlined above.
Monthly Pregnancy Test

- Pregnancy Test
  - Monthly Pregnancy Test Obtained

Information

Confirm that a pregnancy test has been obtained within the last month for this patient.

The prescriber must notify the REMS Coordinating Center (by phone at (888) 301-0333) of any pregnancies that occur during treatment or within one month of discontinuation.
DR. Test Prescriber D.O.
NPI: 1111111112

Program Status: Enrolled as of 3/4/2019

Jenn A Patient
Date of Birth: 6/13/1970

View RDA

- REMS Dispense Authorization (RDA) Verified
dc66a23a

- RDA expires at midnight on 4/3/2019

CONTINUE
DR. Test Prescriber D.O.
NPI: 1111111112

Jenn A Patient
Date of Birth: 6/13/1970

Reproductive Status
Select the female patient's current reproductive status below

Females of Reproductive Potential:
- **Female of Reproductive Potential** - includes girls who have entered puberty and all women who have a uterus and have not passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or postsurgical from bilateral oophorectomy. For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal).

Females of Non-Reproductive Potential:
- **Pre-pubertal Female** - includes females who are at Tanner Stages 1 and 2.
- **Post-menopausal Female** - females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or postsurgical from bilateral oophorectomy.
- **Other medical reasons for permanent, irreversible infertility**

Reason for change in classification
- **Physiological transition**
- **Medical/Surgical (Please specify below)**
- **Other (Please specify below)**

Please Specify

Pregnancy Test
A negative pregnancy test has been confirmed prior to prescribing ambrisantan
- **Yes**
- **No**

Program Status: Enrolled as of 3/4/2019

Information
To change a patient's reproductive status:
1. Select the patient's current reproductive status
2. For a female of reproductive potential, indicate that a negative pregnancy test has been confirmed
Disenroll Patient

Disenroll Reason
- Inactivity
- [ ] Stopped Treatment

Patient Information
- [ ] I have verified the patient's name and date of birth above and would like to disenroll the patient.

Information
Used to disenroll a patient. Once disenrolled, the patient will be removed from the Manage Patients screen.

DISENROLL PATIENT
Pharmacy

- How does a patient enroll in the PS-Ambrisentan REMS?
  Only female patients are required to enroll in the REMS. To enroll a female, the prescriber must complete a Patient Enrollment and Consent Form. The form may be completed and submitted online via the REMS website, through the REMS mobile apps, or by printing and faxing a completed form to the REMS Coordinating Center.

- How does a pharmacy enroll in the PS-Ambrisentan REMS?
  In order to dispense ambrisentan, the pharmacy must be enrolled. Pharmacies must complete an enrollment form specific to its pharmacy type (outpatient or inpatient). Additional information can be found in the Pharmacy Guide.

- What are the PS-Ambrisentan REMS requirements for pharmacies?
- What are the pharmacy types for which a pharmacy can be classified?
- How does a pharmacy validate or obtain a REMS Dispense Authorization (RDA)?

Find A Pharmacy

Find a pharmacy participating in the PS-Ambrisentan REMS.

Enroll

Pharmacies that dispense ambrisentan must be specially certified to enroll in the PS-Ambrisentan REMS.
Pharmacy Enrollment

Instructions

Pharmacies that dispense ambrisantan must be specially certified and enrolled in the PS-Ambrisantan REMS (even if previously enrolled in the Letairis REMS). To become certified, an authorized representative of the pharmacy must first read the Pharmacy Guide, and then agree to follow the PS-Ambrisantan REMS requirements by completing the applicable Pharmacy Enrollment and Agreement Form.

Overview of online enrollment:

1. **Pharmacist Information** - The authorized representative will be asked to provide their name, title, and credentials. The authorized representative will also be asked to provide an email and phone number as well as additional information about the best time and way to be contacted.

2. **Create Password** - The authorized representative will be asked to enter a password to create a program account. Upon creation of the account, the authorized representative will receive an email with a link. Upon clicking on the link in the email, the authorized representative will be asked to log in and complete the enrollment.

3. **Pharmacy Type Selection** - An authorized representative must select the specific pharmacy type for the pharmacy being enrolled.

4. **Pharmacy Information** - The authorized representative will enter the pharmacy's organizational National Provider Identifier (NPI) number. This will be used to obtain most of the information needed for enrollment.

5. **Agreement** - The authorized representative will be asked to provide their signature. By signing, the authorized representative agrees that the pharmacy will comply with the PS-Ambrisantan REMS requirements for the pharmacy type.

6. **Complete** - The enrollment will be completed upon agreeing and providing a signature.
Pharmacy Type Selection

Carefully select a pharmacy type from the list below. Each type of pharmacy in the PS-Ambrisentan REMS has specific requirements.

Central Fill Pharmacy
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 certified central fill pharmacy may provide a list of the originating pharmacies that may accept an ambrisentan prescription on behalf of the central fill pharmacy.
May enroll online.

Retail Just-In-Time Pharmacy
Retail 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.
May enroll online.

Specialty Pharmacy
A 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.
May only enroll via invitation. Please call (888) 301-0333 to request an invitation.

Inpatient Pharmacy
An inpatient pharmacy is a pharmacy that fills prescriptions on behalf of its health care entity for patients receiving inpatient care.
May enroll online.
Pharmacy Enrollment

Pharmacy Information

Central Fill Pharmacy
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 certified central fill pharmacy may provide a list of the originating pharmacies that may accept an ambrisentan prescription on behalf of the central fill pharmacy.

Please provide an organizational NPI number

NPI Information
DOE GARY
Mailing Address
1111 LION ROAD
SomeWhere, PA 11111

(★ = Primary)
★ 1111111111X - Internal Medicine Pulmonary Disease
Agreement

Please read and accept the following terms:

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 miscategorization 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.

☑ As the authorized representative, I will ensure that all pharmacy dispensing staff are trained on the PS-Ambrisentan REMS requirements prior to dispensing ambrisentan.

Sign

Authorized Representative Signature:

Please use your stylus or mouse to sign your name, Mark Smith, in the box below:

[Signature]

Agreement
Complete

Mark Smith PharmD, as an authorized representative you have successfully completed the pharmacy enrollment for DOE GARY.

You may choose from the following options or navigate to your desired function utilizing the pharmacy menu at the top of the page.

**Central Fill Pharmacy**
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 certified central fill pharmacy may provide a list of the originating pharmacies that may accept an ambrisentan prescription on behalf of the central fill pharmacy.

**Manage Staff Pharmacists**
- Manage Staff Pharmacists
- Verify or obtain a patient REIMS Dispense Authorization (ROA)

**Preferences**
Update your personal preferences.

**Print enrollment form**
Print or download a PDF copy of your completed enrollment form.
Pharmacy Enrollment

Pharmacy Information

Retail Just-In-Time Pharmacy
Retail 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.

Please provide an organizational NPI number

NPI Information
DOE GARY
Mailing Address
1111 LION ROAD
SomeWhere, PA 11111

[★ = Primary]
[★ 111111111X - Internal Medicine Pulmonary Disease}
Agreement

Please read and accept the following terms:

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-day 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.

☑️ As the authorized representative, I will ensure that all pharmacy dispensing staff are trained on the PS-Ambrisentan REMS requirements prior to dispensing ambrisentan.

Authorized Representative Signature:

Please use your stylus or mouse to sign your name, Cheryl Jones, in the box below:

[Signature]

☐ AGREEMENT
Cheryl Jones PharmD, as an authorized representative you have successfully completed the pharmacy enrollment for DOE GARY.

You may choose from the following options or navigate to your desired function utilizing the pharmacy menu at the top of the page.

- **Retail Just-In-Time Pharmacy**
  - Retail 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.

- **Manage Staff Pharmacists**
  - Manage Staff Pharmacists
  - Verify or obtain a patient REMS Dispense Authorization (RDA)

- **Preferences**
  - Update your personal preferences.

- **Print enrollment form**
  - Print or download a PDF copy of your completed enrollment form.
Pharmacy Enrollment

Pharmacy Information

Inpatient Pharmacy
An inpatient pharmacy is a pharmacy that fills prescriptions on behalf of its health care entity for patients receiving inpatient care.

Please provide an organizational NPI number

NPI Information
DOE GARY
Mailing Address
1111 LION ROAD
SomeWhere, PA 11111
(⭐ = Primary)
⭐ 1111111111X - Internal Medicine Pulmonary Disease

Inpatient Pharmacy Type
Nursing Home

Inpatient Pharmacist Position/Title
Head of Pharmacy and Therapeutics (P&T)
Agreement

Please read and accept the following terms:

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.

☑️ As the authorized representative, I will ensure that all pharmacy dispensing staff are trained on the PS-Ambrisentan REMS requirements prior to dispensing ambrisentan.

SIGN TYPE SIGNATURE

Authorized Representative Signature:

Please use your stylus or mouse to sign your name, Nick Wentz, in the box below:

[Signature]

AGREEMENT
Complete

Nick Wentz PharmD, as an authorized representative, you have successfully completed the pharmacy enrollment for DOE GARY.

You may choose from the following options or navigate to your desired function utilizing the pharmacy menu at the top of the page.

Inpatient Pharmacy
An inpatient pharmacy is a pharmacy that fills prescriptions on behalf of its health care entity for patients receiving inpatient care.

Manage Staff Pharmacists
- Manage Staff Pharmacists
- Verify or obtain a patient REMS Dispense Authorization (RODA)

Preferences
Update your personal preferences.

Print enrollment form
Print or download a PDF copy of your completed enrollment form.
Instructions

Pharmacies that dispense ambrisentan must be specially certified and enrolled in the PS-Ambrisentan REMS (even if previously enrolled in the Letairis REMS). To become certified, an authorized representative of the pharmacy must first read the Pharmacy Guide, and then agree to follow the PS-Ambrisentan REMS requirements by completing the applicable Pharmacy Enrollment and Agreement Form.

Overview of online enrollment:

1. **Confirm Invitation Information** - The authorized representative will confirm the pharmacy and pharmacist information.

2. **Create Password** - The authorized representative will be asked to enter a password to create a program account. Upon creation of the account, the authorized representative will receive an email with a link. Upon clicking on the link in the email, the authorized representative will be asked to log in and complete the enrollment.

3. **Agreement** - The authorized representative will be asked to provide their signature. By signing, the authorized representative agrees that this pharmacy will comply with the PS-Ambrisentan REMS requirements for the pharmacy type.

4. **Complete** - The pharmacy enrollment will be completed upon agreeing and providing a signature.
Invited Pharmacy Enrollment

Confirm Invitation Information

Authorized Pharmacist:
HANK BOSWELL PharmD

testaccount8@examoto.com

Pharmacy:
SPECIALTY CO.
153 W HILL ST
MS 790
DANVILLE, CA 95028

Taxonomies:
1 332B00000X - Durable Medical Equipment & Medical Supplies
1 3336C0000X - Pharmaceutical/Pharmacy Community/Retail Pharmacy
1 3336S0001X - Pharmacy Specialty Pharmacy
1 333600000X - Pharmacy

PREVIOUS  NEXT  RESTART
Agreement

Please read and accept the following terms:

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 prescription 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 manufacturer 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.

☑ As the authorized representative, I will ensure that all pharmacy dispensing staff are trained on the PS-Ambrisentan REMS requirements prior to dispensing ambrisentan.

Authorized Representative Signature:

Please use your stylus or mouse to sign your name, HANK BOSWELL, in the box below:

[Signature]

Agreement
Complete

HANK BOSWELL PharmD, as an authorized representative you have successfully completed the pharmacy enrollment for SPECIALTY CO.

You may choose from the following options or navigate to your desired function utilizing the pharmacy menu at the top of the page.

**Specialty Pharmacy**
A 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.

**Manage Staff Pharmacists**
- Manage Staff Pharmacists
- Verify or obtain a patient REMS Dispense Authorization (RDA)

**Preferences**
Update your personal preferences.

**Print enrollment form**
Print or download a PDF copy of your completed enrollment form.
### Assigned Pharmacists

<table>
<thead>
<tr>
<th>Name</th>
<th>Current Status</th>
<th>Status Date</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eight Eighteen PharmD</td>
<td>Enrolled</td>
<td>3/4/2019</td>
<td></td>
</tr>
<tr>
<td>Seven Seventeen PharmD</td>
<td>Enrolled</td>
<td>3/4/2019</td>
<td></td>
</tr>
<tr>
<td>Authorized Representative</td>
<td>Pharmacy Staff</td>
<td>Inactivity</td>
<td>Resend Invite, Remove Pharmacy Staff</td>
</tr>
</tbody>
</table>

### Materials for Pharmacies

- Pharmacy Guide
- Outpatient Pharmacy Enrollment and Agreement Form
- Inpatient Pharmacy Enrollment and Agreement Form
- Guide for Female Patients
- Pharmacy FAQs
Verify REMS Dispense Authorization (RDA)

Enter the RDA provided by the patient

13f1430e

Or enter the patient's name and date of birth to search for a valid RDA

First Name   M. I.   Last Name
First Name   Last Name

Date of Birth
mm/dd/yyyy

Information

Verify that the patient has a valid REMS Dispense Authorization (RDA) for this prescription. Enter the RDA provided by the patient or enter the patient's name and date of birth.
Verify REMS Dispense Authorization (RDA)

- REMS Dispense Authorization (RDA) Verified
- 2a1ee931
- RDA expires at midnight on 4/4/2019

Confirm the patient information then select the NDC code and days' supply being dispensed

<table>
<thead>
<tr>
<th>Patient Information</th>
<th>NDC Code</th>
<th>days' supply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Patient, Jenn</td>
<td>Name 1 Capsules nnnmg Total 30</td>
<td>30</td>
</tr>
</tbody>
</table>

No Counseling Record for Patient

The patient has not received her monthly counseling. Please choose from one of the following options:
1. You may counsel the patient using the following guideline here.
2. Call the REMS Coordinating Center at 1-888-301-0333 to receive the counseling guideline and then provide counseling to the patient.
3. Direct the patient to call the REMS Coordinating Center at 1-888-301-0333 to receive the counseling.

☐ I certify that I have done one of the above.
## Verify REMS Dispense Authorization (RDA)

- **REMS Dispense Authorization (RDA) Verified**
  - 324r5t6y

**Information**

A valid RDA has been found. Verify the patient information is correct then enter the NDC code and the days' supply that is being dispensed for this fill.

**Confirm the patient information then select the NDC code and days' supply being dispensed**

<table>
<thead>
<tr>
<th>Patient Information</th>
<th>NDC Code</th>
<th>days' supply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Patient, Test</td>
<td>Name 1 Capsules nmg Total 30</td>
<td>30</td>
</tr>
</tbody>
</table>

**Date of Birth:** 8/13/1978
Verify REMS Dispense Authorization (RDA)

- A prescription fill has been recorded for the following REMS Dispense Authorization (RDA)

  13f1430e

  Pharmacy: JOHNS PHARMACY, L.L.C.
  Authorized Representative: Seven Seventeen PharmD
  Patient Name: Patient, Jenn
  Date of Birth: 6/13/1970 12:00:00 AM
  NDC Code: NDCCode TEST A
days' supply: 30

Program Status: Enrolled as of 3/4/2019

Information

A prescription fill has been recorded for the RDA. The prescription may now be dispensed to the patient.

VERIFY ANOTHER RDA
Verify REMS Dispense Authorization (RDA)
Enter the RDA provided by the patient

Or enter the patient's name and date of birth to search for a valid RDA

First Name  M. I.  Last Name  Date of Birth
Mary   A   Smith  01/23/1978

There are some errors, please correct the items below:
- Patient cannot be found, please check the patient's name and date of birth. If the information is correct, please instruct the patient to call the REMS Coordinating Center at (888) 301-0333
Invite Staff Pharmacist

Name
- First Name
- Last Name

Position/Title
- Position or Title

Credentials
- Select Type

Email
- Email
- Confirm Email

As the authorized pharmacist, I agree that I am responsible for all the pharmacists at this pharmacy.

SEND INVITE
Prescriber Enrollment

Password

Your username is your NPI number

1000000099

Please create your password

CrowdCrowdCrowdCrowdCrowdCrowdCrowdCrowdCrowd

Two-Factor Authentication Enabled

Two-Factor Authentication
Two-factor authentication (2FA) adds a second level of authentication to an account login. In addition to something the user knows, such as a username and password, a user is required to supply something they have. With 2FA disabled, the user is required to provide their username and password. With 2FA enabled, the user is required to additionally enter a unique code that is provided through an SMS text, an email, or an authenticator app. 2FA is configured to use email by default. This can be changed via Preferences after account creation.

NEXT →
Forgot Password?

Enter your email address to reset your password.

Email

testaccountb@examoto.com

RESET
Manage Your Security Settings

Add Authenticator App

Follow these steps to use an authenticator app:

1. Download a two-factor authenticator app like Microsoft Authenticator for Windows Phone, Android and iOS or Google Authenticator for Android and iOS.

2. Scan the QR Code or enter this key into your two-factor authenticator app: xiq0 optj jiqt ndns h3me ndf7 rlre ndcw. The spaces are not required, and the code is not case-sensitive.

3. Once you have scanned the QR code or input the key above, your two-factor authentication app will provide you with a unique code. Enter the code in the confirmation box below and select VERIFY.

VERIFY
Demographics

Name: Jenn A Patient
Username: JennJD

Address:
- 1234 Road Ave
- Address Line 2
- City: Pennsylvania, 12345

Date of Birth: 06/13/1970
Home Phone: (nnn) nnn-nnnnn
Mobile Phone: (610) 444-5555

If necessary, how should we contact you?
- Email
- Text To Mobile
- Phone Call

In general, what is the best time to contact you?
- Morning
- Afternoon
- Evening

Options

DEMOGRAPHICS
ALTERNATE CONTACT INFORMATION
REMINDERS
CHANGE ACCOUNT INFORMATION
DR. Test Prescriber D.O.
NPI: 1111111112

Program Status: Enrolled as of 3/4/2019

Demographics

Name
M. I. Last Name

Test A Prescriber

Mobile Phone

If necessary, how should we contact you?

Email Text To Mobile Phone Call

In general, what is the best time to contact you?

Morning Afternoon Evening

Options

SAVE
Demographics

First Name
Seven

Last Name
Seventeen

Email
1111111117@examoto.com

Mobile Phone
(123) 456-7890

If necessary, how should we contact you?

Email
Phone Call

In general, what is the best time to contact you?

Morning
Afternoon
Evening

SAVE
Set Reminders

Monthly Pregnancy Test

<table>
<thead>
<tr>
<th>Reminder</th>
<th>Time of Day</th>
<th>Method</th>
<th>Days Before</th>
</tr>
</thead>
<tbody>
<tr>
<td>One</td>
<td>Morning</td>
<td>Text To Mobile</td>
<td>9</td>
</tr>
<tr>
<td>Two</td>
<td>Morning</td>
<td>Text To Mobile</td>
<td>6</td>
</tr>
<tr>
<td>Three</td>
<td>Morning</td>
<td>Text To Mobile</td>
<td>3</td>
</tr>
</tbody>
</table>

Please note, if you have not notified us of your monthly pregnancy test or have not completed your monthly counseling, we are required by the REMS to call you regardless of the preferences set above.

SAVE

Options

- DEMOGRAPHICS
- ALTERNATE CONTACT INFORMATION
- REMINDERS
- CHANGE ACCOUNT INFORMATION
**Set Reminders**

**Reproductive Status**

<table>
<thead>
<tr>
<th>Reminder One</th>
<th>Time of Day</th>
<th>Method</th>
<th>Days Before</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Morning</td>
<td>Email</td>
<td>30</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reminder Two</th>
<th>Time of Day</th>
<th>Method</th>
<th>Days Before</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Morning</td>
<td>Email</td>
<td>15</td>
</tr>
</tbody>
</table>

Please note, if you have not completed a patient’s annual reproductive status within 10 days of the anniversary date of the previous classification, we are required by the REMS to call you regardless of the preferences set above.

**Options**

- Demographics
- Office Contact
- Reminders
- Update from NPI
- Change Account Information

**SAVE**
Update NPI Information

Use the information below to determine if you need to refresh your NPI data.

The PS-Ambrisentan REMS last updated your data from NPI on: 11/6/2017 7:29:18 AM

The data at NPI was last updated on: 7/7/2007 8:00:00 PM

REFRESH INFORMATION FROM NPI
Patients

1. What is ambrisentan?

Ambrisentan is a prescription medicine used to treat pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs. Ambrisentan can improve your ability to exercise and it can help slow down the worsening of your physical condition and symptoms. It is not known if ambrisentan is safe and effective in children.

2. What are the serious risks of ambrisentan?

Ambrisentan can cause serious birth defects if taken during pregnancy. Females must not be pregnant when they start taking ambrisentan or become pregnant while taking ambrisentan, or for one month after stopping ambrisentan.

3. What is the PS-Ambrisentan Risk Evaluation and Mitigation Strategy (REMS)?

Because of the risk of serious birth defects, the FDA has required a special program called a Risk Evaluation and Mitigation Strategy (REMS) for ambrisentan. The purpose of the REMS is to make sure the benefits of ambrisentan outweigh the risks. All females must enroll in the PS-Ambrisentan REMS to receive ambrisentan, even if you have been previously enrolled in the Letairis REMS. Specific requirements apply to females who can get pregnant.

4. Is this REMS mandatory?

Yes, the PS-Ambrisentan REMS is mandatory for female patients.

5. What are the PS-Ambrisentan REMS requirements for female patients?

Females Who Cannot Get Pregnant:

You are considered a female who cannot get pregnant if you have not yet entered puberty, or you do not have a uterus, or you have gone through menopause, or you are infertile for any other medical reason and this infertility is permanent and cannot be reversed.

Before starting ambrisentan, you must:

- Review the Guide for Female Patients.
- Enroll in the REMS by completing the Patient Enrollment and Consent Form with your prescriber.
- Receive counselling from your prescriber on the risk of serious birth defects (Pre-pubertal females only)

At all times, you must:

- Inform your doctor if there is a change in your ability to become pregnant

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If you have not yet entered puberty and are over the age of 8: Be monitored regularly to see if your ability to become pregnant changes and tell your prescriber if your ability to become pregnant changes.

If you are the parent or caregiver of a female child who started taking ambrisentan before reaching puberty, you should check your child regularly to see if she is developing signs of puberty. Tell your doctor right away if you notice that she is developing breast buds or pubic hair. Your doctor should decide if your child has reached puberty. **Your child may reach puberty before having her first menstrual period.**

**Females Who Can Get Pregnant:**

You are considered to be a female who can get pregnant if you have entered puberty, have a uterus, and have not gone through menopause.

Before starting ambrisentan, you must:

- Review the *Guide for Female Patients*.
- Get a pregnancy test. Your doctor orders the pregnancy tests for you.
- Enroll in the REMS by completing the *Patient Enrollment and Consent Form* with your prescriber.
- Receive counseling from your prescriber on the risk of serious birth defects, the need to use highly reliable birth control during treatment and for one month after stopping treatment, and emergency birth control.

Before each prescription while taking ambrisentan, you must:

- Receive counseling from the REMS Coordinating Center or the healthcare provider who dispenses ambrisentan on the risk of serious birth defects, the need to use highly reliable birth control during treatment and for one month after stopping treatment, emergency birth control, to get monthly pregnancy tests, and to report a pregnancy immediately.
- Get a pregnancy test. Your doctor orders the pregnancy tests for you. The REMS Coordinating Center will contact you to ask if you have taken this test before ambrisentan is refilled. **Be sure you get your monthly pregnancy test as ordered by your doctor. If you do not get your pregnancy test every month, you may not receive your ambrisentan on time.**

Do not have unprotected sex. Use appropriate birth control during your ambrisentan treatment and for 1 month after stopping your ambrisentan treatment because the medicine may still be in your body.

Talk to your doctor or pharmacist right away if you have unprotected sex, if you think your birth control has failed, or if you think you may be pregnant. Your doctor may tell you to use emergency birth control. Do not wait until your next appointment to tell your doctor if you miss your menstrual period or if you think you may be pregnant.

6. **How do I enroll in the PS-Ambrisentan REMS?**
If you are a female patient, you must be enrolled in the PS-Ambrisentan REMS to receive ambrisentan, even if you have been previously enrolled in the Letairis REMS. Follow these steps with your doctor:

a. Read and understand the Guide for Female Patients, which can be found on the PS-Ambrisentan REMS website: PSAmbrisentanREMS.com.
b. Talk with your doctor to ensure the benefits outweigh the risks of ambrisentan
c. Ask questions. Make sure you understand what you need to do to enroll and take part in the REMS. Make sure you know how to receive and take ambrisentan
d. You and your doctor will fill out the Patient Enrollment and Consent Form. After you read and sign it, your doctor will submit it to the REMS Coordinating Center. The form may be completed and submitted online via the REMS website, through the REMS mobile apps, or by printing and faxing a completed form to the REMS Coordinating Center at 1-888-870-1819.
e. You will select your preferred method of contact during enrollment (text, email, push notification to a mobile app, or phone call).

7. Can I be pre-enrolled in the PS-Ambrisentan REMS?
   a. Your doctor must complete the enrollment, but you can start the enrollment with the Patient Pre-Enrollment process on either the REMS website (www.PSAmbrisentanREMS.com) or the patient mobile app.
   b. You will enter information such as your name, address, phone number, date of birth, and email address. When you are done, you will receive a "Patient Pre-Enrollment Confirmation Number." Give this number to your doctor to complete your enrollment.

8. Do patients need to enroll in the PS-Ambrisentan REMS if already enrolled in the Letairis REMS?
   Yes. You must be enrolled in the PS-Ambrisentan REMS, even if already enrolled in the Letairis REMS.

9. Do male patients taking ambrisentan need to enroll?
   No, males are not required to enroll in the PS-Ambrisentan REMS.

10. What are birth control options for female patients taking ambrisentan?
    Talk to your doctor if you have questions about your birth control options. Tell your doctor if you want to change your birth control method. Information about birth control options can be found in the Guide for Female Patients.

11. How will I receive my ambrisentan?
    Your prescription must be filled by a pharmacy enrolled in the PS-Ambrisentan REMS. Both community and specialty pharmacies participate in the PS-Ambrisentan REMS. You should decide what type of pharmacy is best for you.
You and your doctor can find a list of pharmacies enrolled in the REMS on the REMS website, www.PSAmbrisentanREMS.com. You may also contact your insurance carrier for help in knowing which pharmacies and ambrisentan products are supported by your current insurance plan.

How you receive your prescription will depend on which pharmacy you choose. Some pharmacies may mail your prescription to you while others may give you your prescription at your local pharmacy.

If you are a female who can get pregnant, each month you will be contacted by your preferred method of contact to confirm that you have taken a monthly pregnancy test before refilling your prescription. It is important that you are able to be contacted in order to avoid delays in your refills. Once the monthly pregnancy test has been confirmed, you will receive a REMS Dispense Authorization (RDA) through your preferred method.

You will need an RDA to get your prescription filled. Show this RDA to the pharmacist. If you do not have an RDA, the pharmacist may call the REMS Coordinating Center or check the PS-Ambrisentan REMS website to confirm if an RDA has been given. If an RDA has not been given, the pharmacist will ask you to contact the REMS Coordinating Center to confirm that you have had your monthly pregnancy test.

12. What is an RDA?

An RDA is a REMS Dispense Authorization and is necessary for the pharmacy to obtain in order to fill a prescription for ambrisentan for a female patient. An RDA is generated once it is confirmed that the prescriber and patient are enrolled, and for a female of reproductive potential, a pregnancy test has been completed. See question 11 for more information.

13. What should a patient do if she gets pregnant while taking ambrisentan?

Talk to your doctor or pharmacist right away if you have unprotected sex, if you think your birth control has failed, or if you think you may be pregnant. Your doctor may tell you to use emergency birth control. Do not wait until your next appointment to tell your doctor if you miss your menstrual period or if you think you may be pregnant.

14. If a patient is unable to get pregnant, does she still need to enroll?

All female patients taking ambrisentan are required to enroll in the PS-Ambrisentan REMS. When completing the enrollment form, your doctor will determine your reproductive status. Pre-pubertal females will be educated using the Guide for Female Patients, which can be found on the REMS website. Female patients that cannot become pregnant will be regularly evaluated for any change in reproductive status. Any change will be documented by your doctor's completion of the Ambrisentan Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form.

15. Where can the medication guide be found for this product?
The medication guide can be found on the PS-Ambrisentan REMS website (PSAmbrisentanREMS.com). A medication guide will also be included with each prescription of ambrisentan.

16. Where can patients fill ambrisentan prescriptions?

Your prescription must be filled by a pharmacy enrolled in the PS-Ambrisentan REMS. A list of enrolled pharmacies can be found by visiting the REMS website (PSAmbrisentanREMS.com). If additional assistance is required, please contact the REMS Coordinating Center at 1-888-870-1819.

17. What does it mean to transfer doctors?

Transferring to another doctor means your current doctor will no longer be able to see any of your information in the PS-Ambrisentan REMS and the REMS will no longer provide information about you to your current doctor. To continue ambrisentan treatment, you will need to find another doctor enrolled in the REMS. You can choose to transfer back to this doctor at any time.

18. If I transfer doctors, will my previous doctor still be able to see my information in the PS-Ambrisentan REMS system?

Once you complete the transfer request below, your current doctor will no longer be able to see any of your information in the REMS. Your current doctor may still have access to his or her own copies of your medical information.

19. Will a transfer cause an interruption in my treatment?

This depends on when you received your last prescription and how quickly you can begin treatment with a new doctor. You should talk to your doctor to ensure that an interruption in treatment does not occur.

20. How does a transfer work?

You may initiate a transfer via the REMS website, through the REMS mobile app or by contacting the REMS Coordinating Center. When you are done, you will receive a Transfer Doctor Confirmation Number via the method from which you initiated the transfer. You will need to provide this Confirmation Number to your new doctor. The doctor will use this Confirmation Number to register you under their care in the PS-Ambrisentan REMS. Once this is complete, your treatment will continue with the new doctor.

Pharmacy

1. How does a patient enroll in the PS-Ambrisentan REMS?

Only female patients are required to enroll in the REMS. To enroll a female, the prescriber must complete a Patient Enrollment and Consent Form. The form may be completed and submitted
online via the REMS website, through the REMS mobile apps, or by printing and faxing a completed form to the REMS Coordinating Center.

2. **How does a pharmacy enroll in the PS-Ambrisentan REMS?**

   In order to dispense ambrisentan, the pharmacy must be enrolled. Pharmacies must complete an enrollment form specific to its pharmacy type (outpatient or inpatient). Additional information can be found in the *Pharmacy Guide*.

3. **What are the PS-Ambrisentan REMS requirements for pharmacies?**

   The REMS requirements for pharmacies depend on the pharmacy type. For specific information on pharmacy requirements, please refer to the *Pharmacy Guide*.

4. **What are the pharmacy types for which a pharmacy can be classified?**

   **Outpatient Pharmacy**

   Pharmacies that dispense ambrisentan for outpatient use must be specially certified to enroll as one of the following pharmacy types. Each of these pharmacy types has specific requirements that must be followed to fill and dispense an ambrisentan prescription:
   - **A retail pharmacy** that agrees to order ambrisentan on a per patient per prescription basis (Just-in-Time (JIT) pharmacy). These pharmacies are the filling pharmacy.
   - **A central fill pharmacy**. Central fill pharmacies are the filling pharmacy.
   - **A specialty pharmacy**. Specialty pharmacies are the filling pharmacy.

   **Inpatient Pharmacy**

   An inpatient pharmacy is a pharmacy that dispenses prescriptions in an inpatient setting such as hospital, nursing home, hospice, asylum/mental facility, assisted living, prison, or rehabilitation. Inpatient pharmacies are a filling pharmacy.

5. **How does a pharmacy validate or obtain a REMS Dispense Authorization (RDA)?**

   **Outpatient Pharmacies**

   The validity of an RDA presented by the patient can be confirmed on the REMS website or by contacting the REMS Coordinating Center and providing the RDA number and the patient’s date of birth from the RDA as well as the pharmacy’s NPI number.

   If the patient does not provide an RDA, the pharmacy must obtain an RDA from the PS-Ambrisentan REMS website (www.PSAmbrisentanREMS.com) or the REMS Coordinating Center by providing the patient’s REMS ID or name, the patient’s date of birth and the pharmacy’s NPI number.

   If an RDA cannot be validated or obtained for the patient, the pharmacy must instruct the patient to call the REMS Coordinating Center to provide the missing information. When a REMS Coordinating Center associate is contacted by the patient, the associate will determine what is preventing the issuance of an RDA.

   Once an RDA is validated or obtained, the pharmacy staff must record the NDC number and days supply of the dispensed drug. This can be done through the REMS Coordinating Center or the
PS-Ambrisentan REMS website. To record this information in the website, the pharmacy staff will first enter the pharmacy’s NPI Number, the RDA number, and the patient’s date of birth followed by the NDC number and days supply.

If monthly counseling has not been completed for the patient when the RDA is issued, the RDA will contain counseling guidelines and a message indicating that the pharmacist may:

a. Counsel the patient using the counseling guidelines on the RDA
b. Call the REMS Coordinating Center to receive counseling guidelines and then counsel the patient
c. Instruct the patient to call the REMS Coordinating Center to receive counseling

Inpatient Pharmacies

An RDA is not required for inpatient pharmacies. Enrolled inpatient pharmacies attest that:

a. Processes and procedures are in place to ensure the PS-Ambrisentan REMS requirements are met for female patients.
b. Ambrisentan is dispensed to female patients under the supervision and care of a certified prescriber.
c. Ambrisentan will be dispensed to a female patient after verifying the female patient’s reproductive status, and that she is enrolled in the REMS or will be enrolled prior to discharge.
d. For females of reproductive potential: Verify that 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.
e. No more than a 15-day temporary supply of ambrisentan will be dispensed upon discharge of a female patient.

6. Does a pharmacy need to enroll in the PS-Ambrisentan REMS if already enrolled in the Letairis REMS?

Yes. You must be enrolled in the PS-Ambrisentan REMS, even if already enrolled in the Letairis REMS.

7. Can a chain pharmacy create an account to enroll and manage multiple pharmacies?

This functionality is not supported at this time; however, a chain pharmacy corporation may provide to the REMS a list of its originating pharmacies that will be supported by its central fill pharmacies. The REMS will add these pharmacies to the “Find a Pharmacy” list of available pharmacies that are able to fill an ambrisentan prescription.

Prescribers

1. How do patients enroll in the PS-Ambrisentan REMS?
Upon receipt of a completed Patient Enrollment Form, a REMS Coordinating Center Associate will ensure that the prescriber submitting the Patient Enrollment Form is enrolled in the REMS. Upon confirmation of an enrolled prescriber, the associate will enter the information into the REMS system completing the patient’s enrollment and linking the enrolled patient with the enrolled prescriber. An enrolled prescriber may also enroll female patients through the REMS website or mobile app. Both the prescriber and patient (or parent/guardian for minors) must sign the form.

2. How do prescribers enroll in the PS-Ambrisentan REMS?

To become certified, a prescriber must complete and submit the Prescriber Enrollment and Agreement Form. The form may be completed and submitted online via the REMS website, through the REMS mobile app, or by printing and faxing a completed form to the REMS Coordinating Center.

3. What are the PS-Ambrisentan REMS requirements for prescribers?

Health Care Providers who prescribe ambrisentan must:

To become certified to prescribe

- Review the drug’s Prescribing Information.
- Review the Prescriber Guide.
- Enroll in the REMS by faxing a completed Prescriber Enrollment Form to the REMS Coordinating Center at 1-888-870-1819. Enrollment may also be completed online at www.PSAmbrisentanREMS.com or on the prescriber mobile app.

For all females:

- I will determine the reproductive potential status of all female patients using the definitions provided in the Prescriber Guide and document and submit the results to the REMS using the Patient Enrollment Form.
- I will counsel all female patients that ambrisentan is only available through a restricted distribution program called the PS-Ambrisentan REMS.
- I will enroll all female patients by completing and submitting the Patient Enrollment Form.

For females of reproductive potential:

- I will counsel Females of Reproductive Potential about the risk of embryo-fetal toxicity, the need to use highly reliable contraception during treatment and for one month following treatment discontinuation, and emergency contraception using the Guide for Female Patients.
- I will assess the pregnancy status of Females of Reproductive Potential by ordering and reviewing a pregnancy test before treatment initiation, before writing each prescription, and for one month after treatment discontinuation.
- I will counsel Females of Reproductive Potential if they are not complying with the required testing or if they are not using appropriate contraception.
For pre-pubertal females:

- I will counsel each Pre-Pubertal Female patient and her parent/guardian about the risk of embryo-fetal toxicity using the *Guide for Female Patients*.
- I will regularly assess the reproductive status of each Pre-Pubertal Female during their treatment with ambrisentan.
- I will assess the reproductive status for Pre-Pubertal Females who are 8 years of age and older and will document and submit findings to the REMS at least annually using the *Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form*.

At all times:

- I will report a change or misclassification in reproductive status to the REMS using the *Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form* within 10 business days of becoming aware of the change in reproductive status.
- I will report pregnancies to the REMS.

Additional information may be found in the *Prescriber Guide*.

4. **How do I find a pharmacy to fill an ambrisentan prescription for patients?**

Pharmacies that dispense ambrisentan must be enrolled in the PS-Ambrisentan REMS. Both community and specialty pharmacies participate in the PS-Ambrisentan REMS. Your patient should decide what type of pharmacy is best for her. You may need to help your patients find a pharmacy enrolled in the PS-Ambrisentan REMS. For a list of enrolled pharmacies, visit PSAmbrisentanREMS.com or call the REMS Coordinating Center at 1-888-301-0333. Your patient may also contact her insurance carrier for assistance in determining what pharmacies and ambrisentan products are supported by her current insurance plan.

5. **Do prescribers need to enroll in the PS-Ambrisentan REMS if already enrolled in the Letairis REMS?**

Yes. You must be enrolled in the PS-Ambrisentan REMS, even if already enrolled in the Letairis REMS.

6. **Do healthcare providers who prescribe ambrisentan have to enroll in the PS-Ambrisentan REMS?**

Healthcare providers who prescribe ambrisentan must be specially certified. To become certified, a prescriber must read the *Prescriber Guide* and the Prescribing Information, enroll in the PS-Ambrisentan REMS, and agree to follow the PS-Ambrisentan REMS prescriber requirements. Prescribers must enroll in the PS-Ambrisentan REMS and comply with the PS-Ambrisentan REMS requirements to prescribe ambrisentan, even if previously enrolled in the Letairis REMS.

7. **What if a patient gets pregnant during treatment with ambrisentan or within one month of discontinuation of treatment?**
Prescribers must notify the REMS Coordinating Center at (888) 301-0333 of any pregnancies that occur during treatment with ambrisentan or within one month of discontinuation of treatment.

8. **Does the PS-Ambrisentan REMS have a mobile app?**

Yes, there is a REMS mobile app for prescribers. Many activities including entering a patient's monthly pregnancy test, entering a patient's reproductive potential status, patient enrollment and more can be completed on the mobile app.

**General FAQs**

1. **What does PS mean?**

PS stands for “Parallel System”, which means that there are two REMS for the same drug that run side by side. These two parallel REMS are the PS-Ambrisentan REMS for some generic formulations of ambrisentan and the Letairis REMS for the brand of ambrisentan called Letairis.

2. **What type of information is collected by the PS-Ambrisentan REMS and who will see it?**

The REMS collects personal information when you enroll in the REMS, when you use REMS services, and when you visit PSAmbrisentanREMS.com. Once you are enrolled with the REMS, you are not anonymous to us.

As a female patient, we collect health-related information from you and your doctor (or a designated agent) to complete requirements to comply with the REMS.

The REMS uses your identifiable personal information to fulfill your requests for products and services, and to contact you on REMS-related matters. Before information is reported to the companies that sponsor the PS-Ambrisentan REMS (i.e., the manufacturers) or the FDA, your personal identifying information is removed. We use aggregated (non-personally identifiable) information to help us understand trends, website performance and patient needs.

Please see the Privacy Policy for complete details.

3. **Why aren’t I receiving emails from the PS-Ambrisentan REMS?**

Because email clients differ, and spam filters sometimes filter legitimate email, the REMS suggests you add the REMS domain to your Safe Senders list in your email client. This will minimize the chance that you will miss an email from the PS-Ambrisentan REMS. Follow the instructions for adding a domain to your Safe Sender list for your email client.

4. **How do I download the PS-Ambrisentan REMS app on my mobile device?**

For an Android, the app is available on Google Play. For Apple iOS the app is available in the Apple App Store. You can find the app by searching for “PS-Ambrisentan REMS”.

5. **What if I need help using the website?**

Call the REMS Coordinating Center for help at 1-888-301-0333.

6. **What browser types and versions does the PS-Ambrisentan REMS website support?**
We support the latest and previous releases of all major browsers on a rolling basis. Each time a new version is released, we begin supporting that version and typically stop supporting the third most recent version. Major browsers include Internet Explorer, Chrome, Firefox, and Safari.

7. **How does the PS-Ambrisentan REMS website use cookies?**

Cookies are used to display the correct alerts and notifications that assist you in complying with the REMS requirements.

We never store your unencrypted sensitive information in a cookie and you can find more information about how we use cookies in our Privacy Policy.

8. **What do I do if I can't view a document on the website?**

If you are attempting to open a document, but nothing appears you may have a pop-up blocker installed on your PC or, in the case of a PDF file, you may not have the Adobe Reader software installed. To rectify this, you can disable the feature in your browser for pop-up blockers. To install Adobe Reader, you can visit the Adobe site here.

9. **How do I report a problem with the PS-Ambrisentan REMS website?**

You may report website problems to the REMS Coordinating Center by calling 1-888-301-0333.

10. **How do I obtain a username and password for the PS-Ambrisentan REMS website?**

Physicians and other appropriately licensed healthcare professionals who prescribe ambrisentan (prescribers) must be specially certified in the PS-Ambrisentan REMS. To become certified, a prescriber must first read the *Prescribing Information* (PI) and the *Prescriber Guide*. The prescriber must then enroll in the PS-Ambrisentan REMS. The enrollment process will create a username and password.

Pharmacies, practitioners, and health care settings that dispense ambrisentan (dispensers) must be specially certified. To become certified, an authorized representative of the pharmacy must read the *Pharmacy Guide*. The authorized representative must then enroll the pharmacy in the PS-Ambrisentan REMS. When a pharmacist enrolls, they create their own credentials. These credentials are for them, when they login they need to specify the store’s NPI number. A pharmacist can be related to more than one pharmacy.

Female patients taking ambrisentan must be enrolled in the PS-Ambrisentan REMS. Your doctor will enroll you. However, to save time at the doctor’s office, you can start the enrollments process using the Pre-Enroll tool found on the Patient page and the Patient App. The enrollment process will create a username and password.

Male patients taking ambrisentan are not enrolled in the PS-Ambrisentan REMS, and therefore do not need a username and password.

11. **What if I do not receive the verification email after I created my account?**

If you haven’t received your verification email, first check your spam and/or junk email folder. If the mail is not present, please call the REMS Coordinating Center at 1-888-301-0333.

12. **What do I do if I forgot my password?**
On the login screen, select “Forgot your password?” and follow the instructions.

13. What do I do if I forgot my username?

If you are a healthcare provider, your username is your individual NPI number. If you are a patient
your username was selected by you at the time of enrollment. If you can’t remember your
username, you can call the REMS Coordinating Center at 1-888-301-0333 for assistance.

14. What do I do if my user account is locked?

If you are locked out of your user account, call the REMS Coordinating Center at 1-888-301-0333

15. How do I change my username and/or password?

Your username cannot be changed. You may however change your password in the Preferences
section of the website. Use the Preferences sub menu under the top far right menu item labeled
Username.

16. What is two-factor authentication (2FA)?

Two-factor authentication can be set in your Preferences and allows for improved security over an
account and login.

Two-factor authentication adds a second level of authentication to an account log-in. In addition
to something you know, such as your user name and password, a user is required to supply
something they have. With 2FA disabled, the user is required to provide their username and
password. With 2FA enabled, the user is required to additionally enter a unique code that is
provided through an SMS text, an email, or an authenticator app. 2FA is configured to use email
by default. This can be changed via Preferences after account creation. The second factors available
in the Ambrisentan REMS are:

- An Authenticator App such as Microsoft Authenticator for Windows Phone, Android and
iOS or Google Authenticator for Android and iOS.
- SMS
- email

We recommend the Authenticator App.