Home Page (Info Pop-up)

XYWAV and XYREM REMS

1-866-997-3688

1-866-470-1744

PRESCRIBING INFORMATION

FAQ

XYWAV and XYREM REMS

PRESCRIBER RESOURCES

PATIENT/CAREGIVER RESOURCES

Welcome to the *NEW* XYWAV and XYREM REMS website!

- With the launch of XYWAV the previous XYREM REMS has now become the XYWAV and XYREM REMS, with a new website.
- The new website combines XYWAV and XYREM in a single REMS, and includes updates such as user-friendly navigation with interactive features.
- All XYWAV and XYREM REMS materials are available here for view or download. Prescriber and patient enrollment is available and can be completed online.
- Prescriptions can now be submitted electronically through our online submission service.

Proceed to Website

Materials | Materials | Enrollment | Enrollment | XYWAV and XYREM

PRESCRIBER MATERIALS

Important Updates for Prescribers

Please be aware that the XYWAV and XYREM REMS Prescription Forms are available for prescribers from the XYWAV and XYREM REMS website within the "Prescribe XYWAV and XYREM" section.

Complete and submit forms online.

OR

Download, print, sign, and fax or mail to the XYWAV and XYREM REMS.

Please review the materials below before enrolling in the XYWAV and XYREM REMS

- Prescribing Information
- Prescriber Brochure
- Prescriber Roles & Responsibilities

Prescriber Materials

- XYWAV Prescription Form
- XYREM Prescription Form
- XYWAV and XYREM REMS Prescriber Enrollment Form
- XYWAV and XYREM REMS Patient Enrollment Form
- XYWAV and XYREM REMS Prescriber Brochure

Patient Materials

- XYREM Patient Quick Start Guide
- XYREM Brochure for Pediatric Patients and their Caregivers
- XYWAV Brochure for Pediatric Patients and their Caregivers
- XYWAV Patient Quick Start Guide

XYWAV and XYREM REMS

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Patient Enrollment

Prescribe XYWAV and XYREM

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Patient Materials

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- XYREM Brochure for Pediatric Patients and their Caregivers
- XYWAV Brochure for Pediatric Patients and their Caregivers
- XYWAV Patient Quick Start Guide

XYWAV and XYREM REMS

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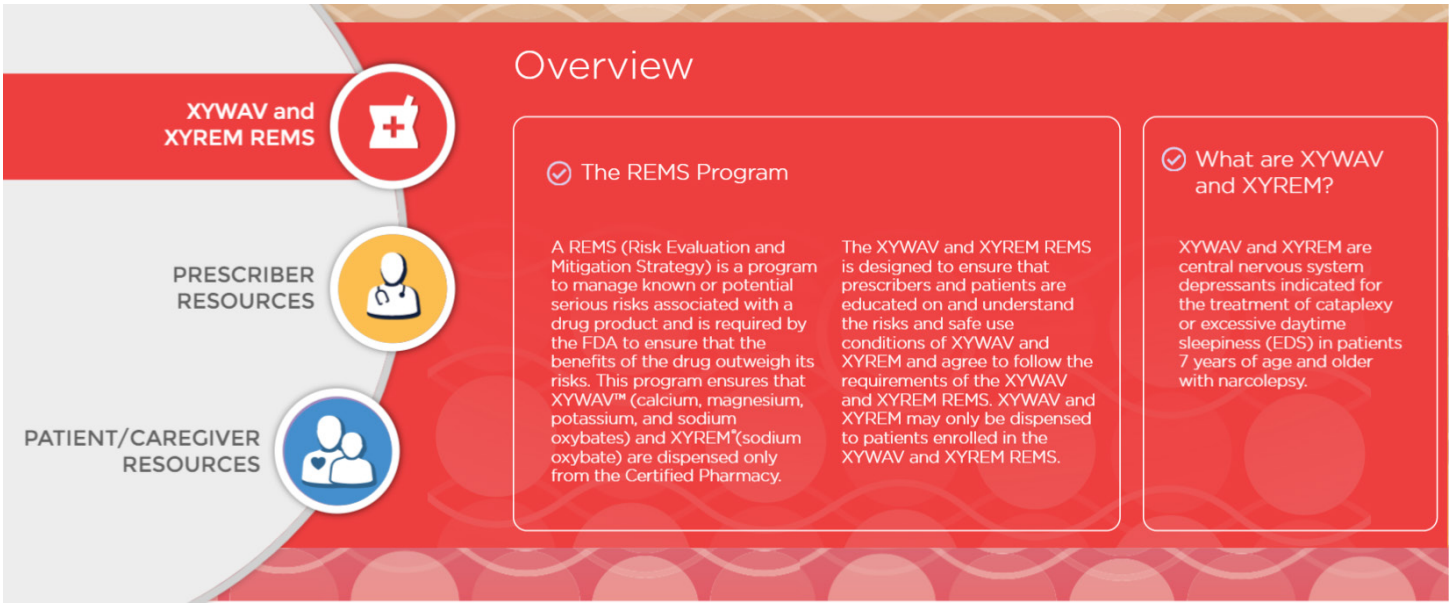
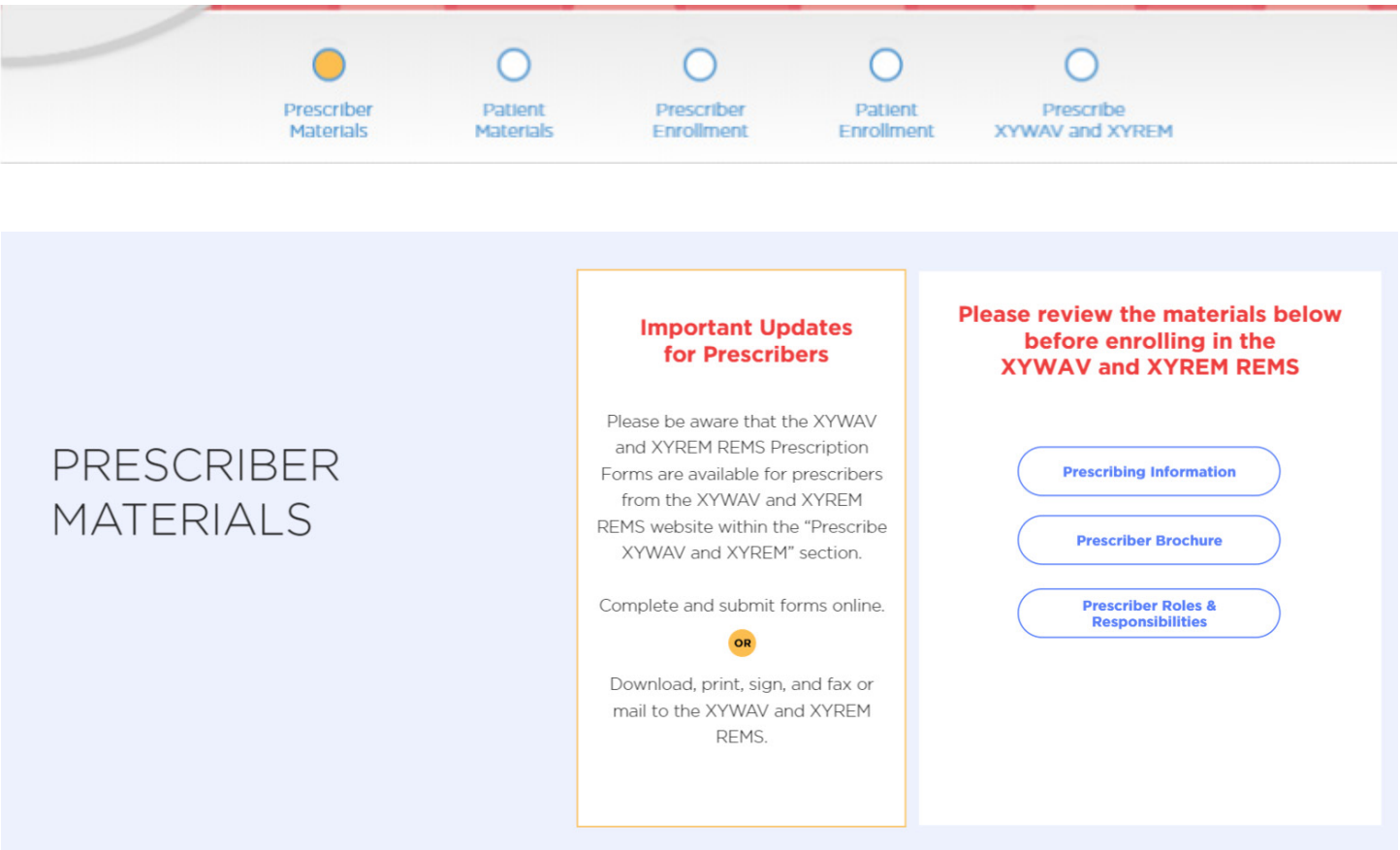
Top Carousel (1 of 4)



Top Carousel (2 of 4)

XYWAV and XYREM REMS
PRESCRIBER RESOURCES
PATIENT/CAREGIVER RESOURCES
Patient/Caregiver Resources
Patient Quick Start Guide
For XYWAV
For XYREM
Brochure for Pediatric Patients and their Caregiver
For XYWAV
For XYREM
What You Should Know
You must be enrolled in the XYWAV and XYREM REMS by your health care provider.
You can only receive XYWAV or XYREM if you are enrolled in the REMS and if there is a record that you have been counselled on the safe use of XYWAV or XYREM
Each pediatric patient must have a caregiver who is counseled by the healthcare provider.
XYWAV and XYREM will be dispensed only by the REMS Certified Pharmacy.

Bottom Carousel (1 of 5)



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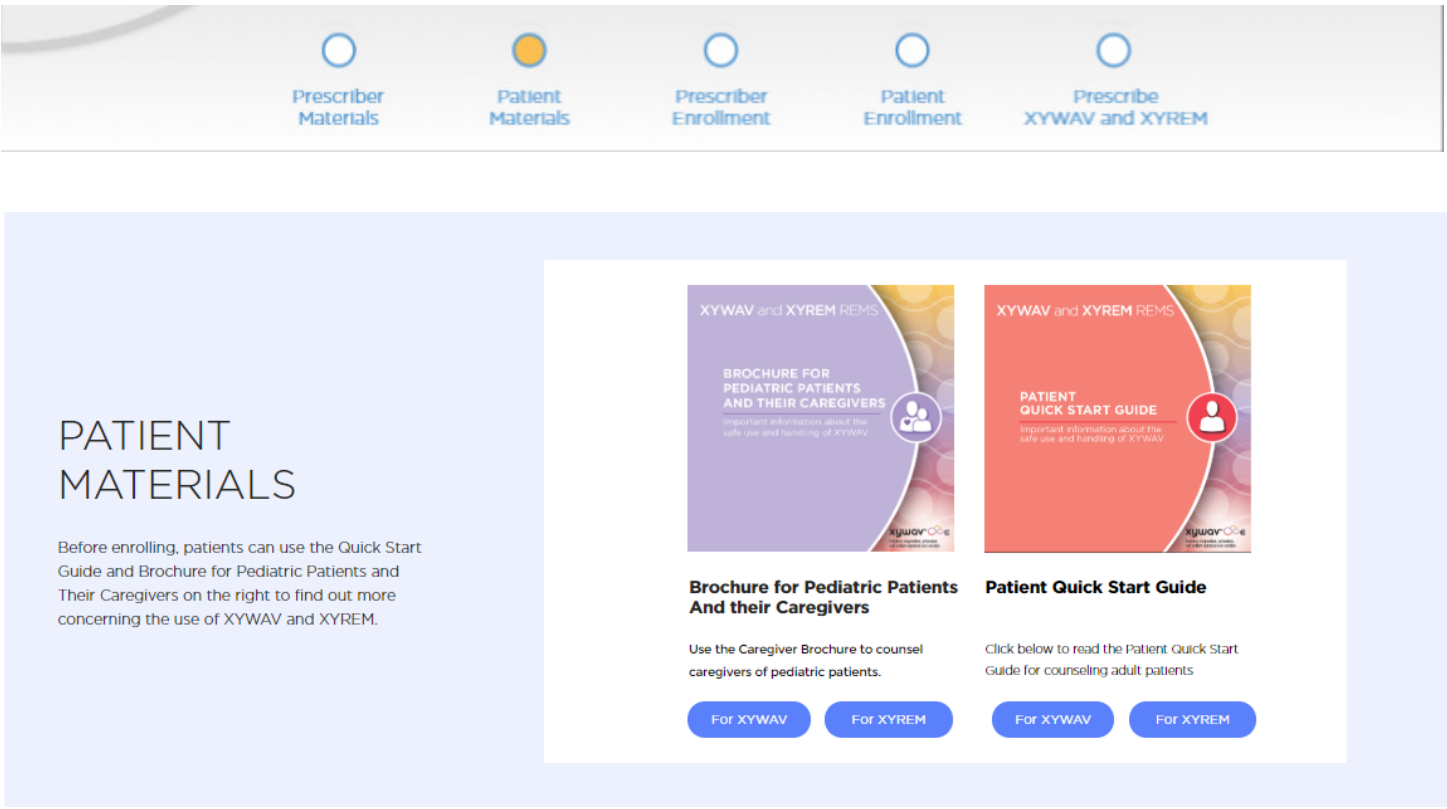

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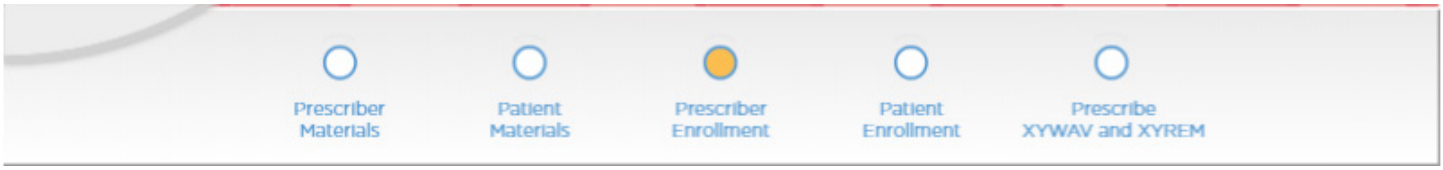

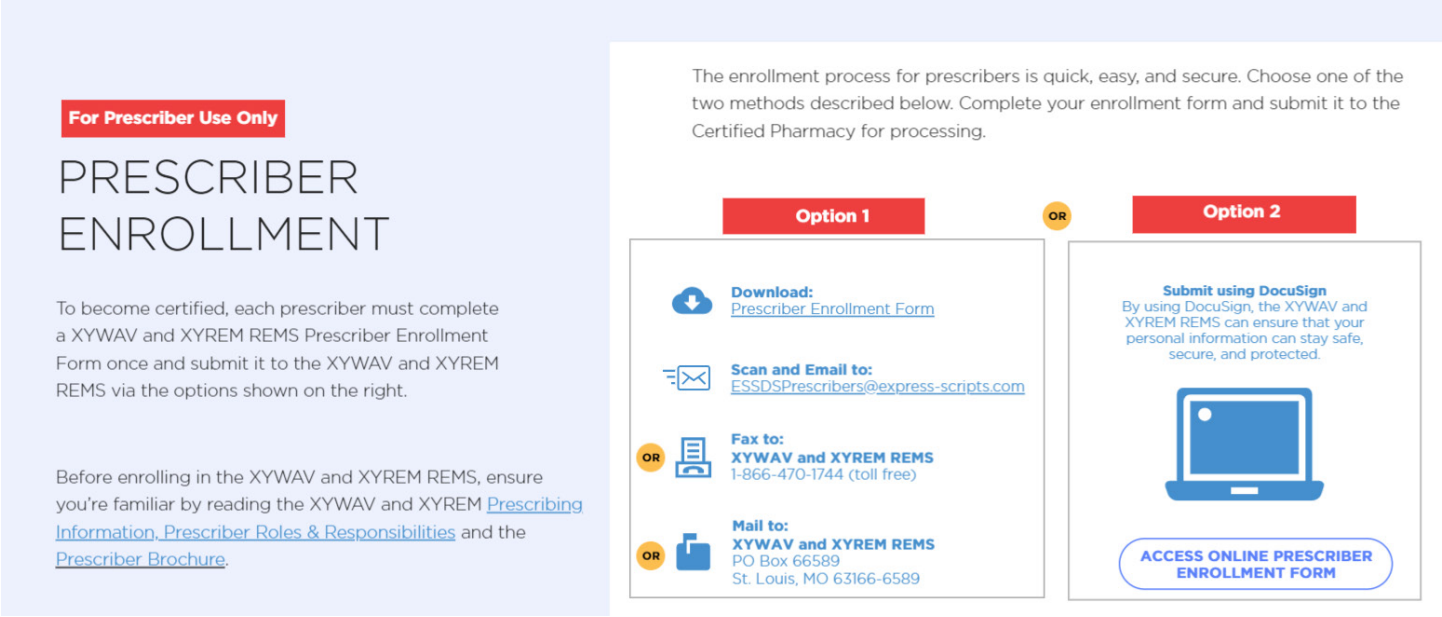

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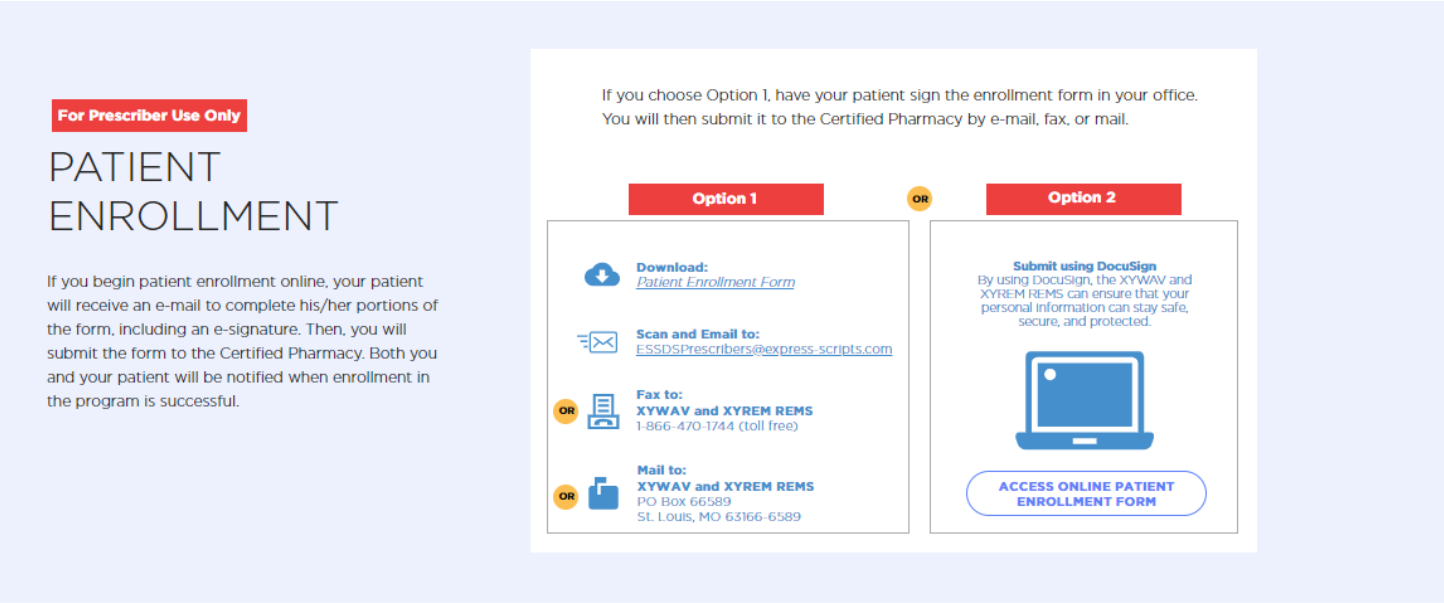


Bottom Carousel (5 of 5)

PRESCRIBE XYWAV and XYREM

Utilize the resources here to understand the benefits and risks of XYWAV and XYREM and to prescribe XYWAV and XYREM. For more information please call the XYWAV and XYREM REMS toll free at 1-866-997-3688.

To prescribe XYWAV and XYREM, both prescriber and patient must be enrolled in the XYWAV and XYREM REMS.

VIEW PRESCRIBING INFORMATION

Download Prescription Forms OR **Online Prescription Forms**

Download the **XYWAV** Prescription Form

OR

Download the **XYREM** Prescription Form

Print and Sign the completed XYWAV or XYREM Prescription Form for your patient

Fax to:
XYWAV and XYREM REMS
1-866-470-1744 (toll free)

OR

Mail to:
XYWAV and XYREM REMS
PO Box 66589
St. Louis, MO 63166-6589

Complete the **XYWAV** Prescription Form Online For Your Patient

OR

Complete the **XYREMS** Prescription Form Online For Your Patient

The Prescription Form will be verified for completeness by the Certified Pharmacy.

You will be notified by the Certified Pharmacy once the Prescription Form is received.

FAQ

Is it still possible to enroll offline?
Yes, you can still enroll offline. Please download the PDF version of this form and follow the submission instructions.

How do I add my signature to an online enrollment?
This is done securely and easily through DocuSign.

Do I need a DocuSign account to complete the online enrollment process?
No. You do not need a DocuSign account to complete the online enrollment process.

Do I need to complete the online version of the prescriber enrollment form if I am already enrolled into the XYWAV and XYREM REMS?
No. If you are already enrolled into the newly approved XYWAV and XYREM REMS or the XYREM REMS or have completed the prescriber enrollment process offline and faxed it to the Certified Pharmacy, you do not need to complete the online version of the prescriber enrollment form.

You can still use the online enrollment form to enroll your patients.

How long does it take to process my enrollment so I can enroll patients?
Generally, the Certified Pharmacy will process your enrollment within 2 to 3 business days.

How will patients be notified that they need to complete their portion of the enrollment form?
Once you initiate the patient enrollment form, an email notification will be sent to your patient. The email will include a link to the enrollment form on DocuSign, where your patient can securely complete their portion of the enrollment process.

If your patient does not complete their portion of the enrollment form, we will send them a series of notification reminder emails.

How can I help my patient complete their portion of the enrollment form?
Due to security and privacy reasons, patients must fill out the entire portion of their form. If additional assistance is needed, we recommend you assist them with the process through a phone call.

Will a patient be able to include a copy of their insurance identification card?
If a patient confirms that they have prescription coverage on the enrollment form, they will be able to include a copy of their insurance identification card as an attachment.

If patients are completing the enrollment form on a mobile device, they will be able to use the camera to take a picture of their identification card.

How do I know my patient's information is safe?
DocuSign provides full document encryption to ensure the security and privacy of your data. Documents stored in their ISO 27001 and SSAE 16 data centers are encrypted with the highest levels of encryption.

Will my or my patient's information be shared with any third parties?
No. Your or your patient's information will be kept strictly confidential and never be shared or sold to third parties.

Prescriber Roles & Responsibilities

Prescribers enrolled in the XYWAV and XYREM REMS agree to perform the following:

1. Review the Prescribing Information (PI) and the XYWAV and XYREM REMS Prescriber Brochure.

2. Screen each patient for:

- History of alcohol or substance abuse

- History of sleep-related breathing disorders

- History of compromised respiratory function

- Concomitant use of sedative hypnotics, other CNS depressants, or other potentially interacting agents

- History of depression or suicidality

3. Counsel each patient prior to initiating therapy with XYWAV or XYREM on the serious risks and safe use and handling of XYWAV and XYREM using the XYWAV and XYREM REMS Quick Start Guide.

4. Enroll each patient in the XYWAV and XYREM REMS by completing the XYWAV and XYREM REMS Patient Enrollment Form and submitting the form to the XYWAV and XYREM REMS.

5. Evaluate each patient within the first 3 months of starting XYWAV and XYREM therapy, including an evaluation of the following. It is recommended that patients be re-evaluated every 3 months thereafter while taking XYWAV and XYREM.

- Concomitant use of sedative hypnotics, other CNS depressants, or other potentially interacting agents

- Serious adverse events

- Signs of abuse and misuse, including:
  i. an increase in dose or frequency of dosing
  ii. reports of lost, stolen, or spilled medication
  iii. drug-seeking behavior

6. Report all potential serious adverse events, including CNS depression, respiratory depression, loss of consciousness, coma, death, and any cases of suspected abuse, misuse, or diversion to Jazz Pharmaceuticals.

Each time a new prescription is written the prescriber will complete the XYWAV and XYREM REMS Prescription Form and submit it to the XYWAV and XYREM REMS. By completing and signing this form, the prescriber acknowledges:

1. Having an understanding of:

- The approved indications for XYWAV and XYREM:

  i. Treatment of cataplexy in narcolepsy

  ii. Treatment of excessive daytime sleepiness in narcolepsy

- The serious risks associated with XYWAV and XYREM

- The Prescribing Information and XYWAV and XYREM REMS Prescriber Brochure

2. Having screened the patient for the following:

- History of alcohol or substance abuse

- History of sleep-related breathing disorders

- History of compromised respiratory function

- Concomitant use of sedative hypnotics, other CNS depressants, or other potentially interacting agents

- History of depression or suicidality

3. Having counseled the patient on:

- The serious risks associated with XYWAV and XYREM Contraindications (alcohol and sedative hypnotics) and implications of concomitant use of XYWAV and XYREM with other potentially interacting agents

- Preparation and dosing instructions for XYWAV and XYREM

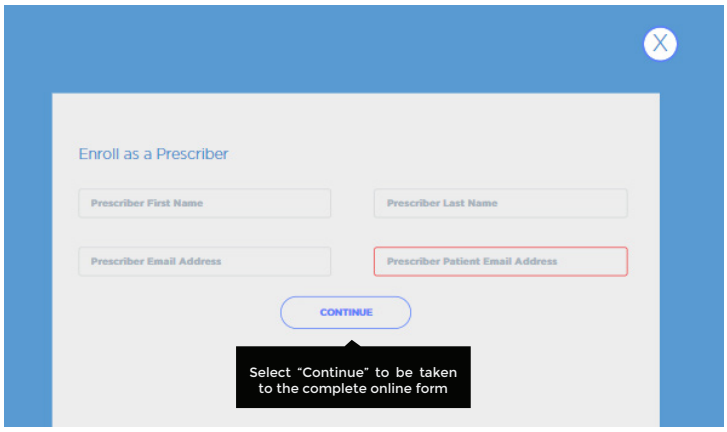
- Risk of abuse and misuse associated with XYWAV and XYREM

- Risk of operating hazardous machinery including automobiles or airplanes for the first 6 hours after taking a dose of XYWAV and XYREM

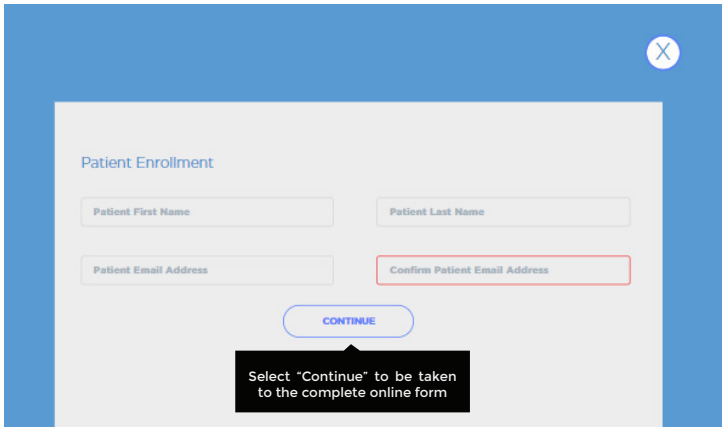
- Safe use, handling, and storage of XYWAV and XYREM

4. That XYWAV and XYREM is medically appropriate for the patient

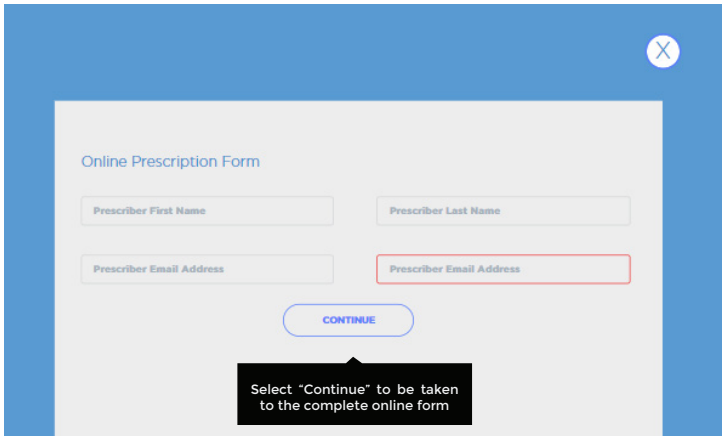
5. Having listed all known prescription and nonprescription medications and doses on the XYWAV and XYREM REMS Prescription Form



Online version of PDF Prescriber Enrollment Form



Online version of PDF Patient Enrollment Form



Online version of PDF Prescrip-tion form

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ERIC P BASTINGS
02/11/2021 09:13:05 AM