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.
- XYWAV and XYREM Prescription Forms are available online.

Proceed to Website

Important Updates for Prescribers

Please be aware that the XYWAV and XYREM Prescription Forms are available for prescribers from the XYWAV and XYREM REMS website within the “Prescribe XYWAV and XYREM” section.
Download, print, sign, and fax or mail to the XYWAV and XYREM REMS.
Important Updates for Prescribers

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

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
Overview

The REMS Program

A REMS (Risk Evaluation and Mitigation Strategy) is a program to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure that the benefits of the drug outweigh its risks. This program ensures that XYWAV® (calcium, magnesium, potassium, and sodium oxybate) and XYREM® (sodium oxybate) are dispensed only from the Certified Pharmacy.

The XYWAV and XYREM REMS is designed to ensure that prescribers and patients are educated on and understand the risks and safe use conditions of XYWAV and XYREM and agree to follow the requirements of the XYWAV and XYREM REMS. XYWAV and XYREM may only be dispensed to patients enrolled in the XYWAV and XYREM REMS.

What are XYWAV and XYREM?

XYWAV and XYREM are central nervous system depressants.

- XYWAV is indicated for the treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy.
- XYWAV is indicated for the treatment of idiopathic hypersomnia (IH) in adults.
- XYREM is indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.
Prescriber Resources
Select the buttons below to view or download.

Enrollment
- Prescriber Enrollment Form
- Patient Enrollment Form

Prescribing Information
- For XY WAV
- For XY REM

Prescription Forms
- For XY WAV
- For XY REM

XY WAV and XY REM Prescriber Brochure
Download

Important Updates for Prescribers
Please be aware that the XY WAV and XY REM Prescription Forms are available for prescribers from the XY WAV and XY REM REMS website within the “Prescribe XY WAV and XY REM” section.

Please review the materials below before enrolling in the XY WAV and XY REM REMS
Prescribing Information
Patient/Caregiver Resources

What You Should Know
- All patients must be enrolled in the XYWAV and XYREM REMS by the patient’s healthcare provider.
- Prescriptions for XYWAV and XYREM are only dispensed and shipped to patients who are enrolled in the REMS with documentation of safe use conditions.
- 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.

Important Updates for Prescribers
Please be aware that the XYWAV and XYREM Prescription Forms are available for prescribers from the XYWAV and XYREM REMS website within the “Prescribe XYWAV and XYREM” section.
Download, print, sign, and fax or mail to the XYWAV and XYREM REMS.
Important Updates for Prescribers

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

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Reference ID: 4935525
PATIENT MATERIALS

Before enrolling, patients can use the Quick Start Guide and Brochure for Pediatric Patients and Their Caregivers on the right to find out more concerning the use of XYWAV and XYREM.

Brochure for Pediatric Patients And their Caregivers

Use the Caregiver Brochure to counsel caregivers of pediatric patients.

Patient Quick Start Guide

Click below to read the Patient Quick Start Guide for counseling adult patients.
The enrollment process for prescribers is quick, easy, and secure. Choose one of the two methods described below. Complete your enrollment form and submit it to the Certified Pharmacy for processing. For best results please use Adobe Acrobat to fill out the forms.

**Option 1**
- Download: [Prescriber Enrollment Form](#)
- Scan and Email to: [ESSDSPrescribers@express-scripts.com](mailto:ESSDSPrescribers@express-scripts.com)
- Fax to: XYWAV and XYREM REMS 1-866-470-1744 (toll free)
- Mail to: XYWAV and XYREM REMS PO Box 66589 St. Louis, MO 63166-6589

**Option 2**
Submit using DocuSign
By using DocuSign, the XYWAV and XYREM REMS can ensure that your personal information can stay safe, secure, and protected.

**ACCESS ONLINE PRESCRIBER ENROLLMENT FORM**
If you choose Option 1, have your patient sign the enrollment form in your office. You will then submit it to the Certified Pharmacy by e-mail, fax, or mail. For best results please use Adobe Acrobat to fill out the forms.

For Prescriber Use Only

PATIENT ENROLLMENT

If you begin patient enrollment online, your patient will receive an e-mail to complete his/her portions of the form, including an e-signature. Then, you will submit the form to the Certified Pharmacy. Both you and your patient will be notified when enrollment in the program is successful.

Option 1

Download:
Patient Enrollment Form

Scan and Email to:
ESSDSPrescribers@express-scripts.com

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

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

Option 2

Submit using DocuSign
By using DocuSign, the XYWAV and XYREM REMS can ensure that your personal information can stay safe, secure, and protected.

ACCESS ONLINE PATIENT ENROLLMENT FORM
Please submit the signed form to the Certified Pharmacy by e-mail, fax, or mail. Online submission is coming soon. For best results please use Adobe Acrobat to fill out the forms.

Download Prescription Forms

Download the XYWAV Prescription Form

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)

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

Online Prescription Forms

Complete the XYWAV Prescription Form Online For Your Patient

Complete the XYREM Prescription Form Online For Your Patient

Print and Sign the Completed XYWAV or XYREM Prescription Form for your Patient

COMING SOON
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.
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 and 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:
     1. an increase in dose or frequency of dosing
     2. reports of lost, stolen, or spilled medication
     3. 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:**
   - Treatment of cataplexy in narcolepsy or treatment of excessive daytime sleepiness in narcolepsy in patients 7 years and older
   - Treatment of idiopathic hypersomnia in adults

   **The approved indications for XYREM:**
   - Treatment of cataplexy in narcolepsy or treatment of excessive daytime sleepiness in narcolepsy in patients 7 years and older

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 or XYREM Prescription Forms