



XYWAV and XYREM REMS Patient Counseling Checklist

(Prior to dispensing XYWAV™ or XYREM® the XYWAV and XYREM REMS Certified Pharmacy ensures the completion of the checklist and its requirements and documents the information received in the XYWAV and XYREM REMS Central Database. Include additional requirements (if any) per federal or state requirements that need to be collected as part of the patient counseling process.)

STEP 1: PATIENT INFORMATION

Prescription for:

- XYWAV
- XYREM

(Complete this section for new patients [first shipment of any oxybate-containing product within the XYWAV and XYREM REMS], existing patients who are restarting XYWAV or XYREM treatment after not receiving either of the drug products for 6 months or longer, and patients who report a new medication or new comorbid medical condition listed in Step 4 of this checklist)

- New/restart
- Scheduled refill
- Early refill approved through RMR process
- Change of care responsibility

Patient Name: _____ **Patient ID Number:** _____

Prescriber Name: _____ **Prescriber ID Number:** _____

For pediatric patients, include caregiver information below.

Caregiver Name: _____ **Caregiver ID Number:** _____

Include Pharmacist name and date time stamp for each section completed.

STEP 2: COUNSELING

(Complete this section ONLY for new patients and existing patients who are restarting XYWAV or XYREM treatment after not receiving XYWAV or XYREM for 6 months or longer)

- Ask if the prescriber reviewed the appropriate XYWAV and XYREM REMS material with the patient/caregiver (XYWAV or XYREM Patient Quick Start Guide for adult patients, XYWAV or XYREM Brochure for Pediatric Patients and Their Caregivers for pediatric patients) and explain that this material will be included with the first shipment.

_____ (Pharmacist Name) _____/_____/_____ (Date/Time)

- Verify that the patient/caregiver has been counseled on **Therapy Expectations** below
 - During clinical trials with XYWAV and XYREM, many patients with narcolepsy saw some improvement with excessive daytime sleepiness and/or cataplexy in the first weeks after beginning therapy. However, the response varies from patient to patient. It may also take time to find the right dose that works for the patient. The prescriber will determine the dose that is appropriate.



- The patient/caregiver should talk to the prescriber about any troubling side effects or if the patient does not feel any benefits while taking XYWAV or XYREM.
- For any prescription changes, the prescriber should call or fax the new prescription change to the pharmacy; patients or caregivers should NEVER attempt to change the dose themselves.

_____ (Pharmacist Name) ____/____/____ (Date/Time)

Verify that the patient/caregiver has been counseled on **Preparation and Administration** information below

- XYWAV/XYREM should be prepared and taken only as directed by the prescriber (review prescriber’s instructions with patient/caregiver). Prepare the first dose by placing ____ grams of XYWAV/XYREM into one of the provided pharmacy containers. Add 1/4 cup of water to the container and turn the cap clockwise (to the right) until it clicks and locks into its child-resistant position. Then, prepare the second dose by placing ____ grams of XYWAV/XYREM into the second pharmacy container, adding about 1/4 cup of water, and closing the pharmacy container. The water does not come with XYWAV/XYREM. The patient/caregiver can use either tap or bottled water. The solution should remain clear, and it will taste salty. Place the containers in a safe place, out of the reach of children or pets.
 - For adult patients, the recommended location for the second dose is a safe place near the patient’s bed.
 - For pediatric patients, it is recommended that the caregiver ensure that all XYWAV/XYREM doses are kept in a safe place until given.
- The patient/caregiver should call the XYWAV and XYREM REMS with any questions regarding how XYWAV/XYREM is to be prepared or taken. The pharmacy is available Monday through Friday, from 7 AM to 8 PM Central Time, at 1-866-997-3688, and a pharmacist is always available, 24 hours a day, 7 days a week, if needed.
- The patient/caregiver should refer to the product Medication Guide for additional information on preparation of doses.
- When the patient is ready to go to sleep, the first dose of XYWAV/XYREM should be taken while sitting in bed and the patient should lie down immediately after dosing.
 - Doses should be taken at least 2 hours after eating.
 - The time that it takes to fall asleep might be different from night to night. The patient may fall asleep quickly, in about 5 to 15 minutes, although some patients have reported falling asleep more quickly (without first feeling drowsy) and others may take longer to fall asleep.
 - The patient/caregiver may want to set an alarm to make sure the patient wakes up to take the second dose. The second dose of XYWAV/XYREM should be taken 2.5 to 4 hours after the first dose of XYWAV/XYREM is taken.
 - If a dose is missed, the patient should NEVER take two doses of XYWAV/XYREM at once.
- The diluted medication MUST be used within 24 hours of preparation. Discard any unused medication down the sink or toilet drain.
- When XYWAV/XYREM can no longer be drawn out of the bottle with the dispensing device, the patient/caregiver should dispose of the bottle. Remind the patient/caregiver to mark out information on the prescription label, including all personal information and the XYWAV/XYREM name, to make it unreadable before throwing out the empty bottle or other empty medicine packaging.
- The patient/caregiver should be sure to store both the XYWAV/XYREM bottle and all prepared doses in a safe and secure place out of the reach of children and pets. Emergency medical help should be sought right away if a child who has not been prescribed XYWAV/XYREM drinks XYWAV/XYREM.
- XYWAV/XYREM should be stored at room temperature.

_____ (Pharmacist Name) ____/____/____ (Date/Time)



Verify that the patient/caregiver has been counseled on **Precautions Needed for XYWAV/XYREM Use**

- XYWAV/XYREM is classified as a controlled substance medication. XYWAV/XYREM must be used only by the person for whom it is prescribed and as directed by the physician. All lost or stolen medication must be reported.
- Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.
- XYWAV/XYREM contains oxybate, which is a form of gamma-hydroxybutyrate (GHB). GHB has been used as a substance of abuse and has been associated with drug-facilitated sexual assault (date rape).
- Abuse of GHB can lead to dependence (a physical need to take the drug), craving for the medicine, and severe withdrawal symptoms (symptoms that start when the drug is stopped, especially when it is stopped suddenly). Abuse of GHB, with or without other central nervous system (CNS) depressants (e.g., nortriptyline, oxycodone, or heroin), including alcohol, can lead to seizure, trouble breathing, decreases in the level of consciousness, coma, and death.

_____ (Pharmacist Name) ____/____/____ (Date/Time)

Verify that the patient/caregiver has been counseled on **Side Effects**

- In clinical trials:
 - in adult patients, the most commonly observed side effects associated with the use of XYWAV included: headache, nausea, dizziness, decreased appetite, parasomnia, diarrhea, hyperhidrosis, anxiety, and vomiting.
 - in adult patients, the most commonly observed side effects associated with the use of XYREM included: nausea, dizziness, vomiting, somnolence, enuresis, and tremor.
 - in pediatric patients, the most commonly observed side effects associated with the use of XYWAV/XYREM included: nausea, enuresis, vomiting, headache, weight decreased, decreased appetite, dizziness, and sleepwalking. Some side effects may be more likely to be observed with higher doses of XYWAV/XYREM.
- XYWAV/XYREM can cause serious side effects, including trouble breathing while asleep, confusion, unusual or disturbing thoughts, depression, and passing out, even at recommended doses. The patient/caregiver should consult with the prescriber if the patient has any of these problems while taking XYWAV/XYREM.
- Patients should not participate in hazardous activities requiring complete mental alertness or motor coordination within the first 6 hours of dosing or after first initiating treatment until certain that XYWAV/XYREM does not affect them adversely.
- When taking XYWAV/XYREM, patients should not drink alcohol or take medicines that make them sleepy, including antidepressants, antipsychotics, anti-epileptics, opioids, general anesthetics, muscle relaxants, and/or illicit CNS depressants (e.g., heroin or GHB).
- These are not all of the side effects that patients may experience. The patient/caregiver should contact the prescriber if there are concerns about any possible side effects. Refer to the product Medication Guide for additional information on possible side effects.

_____ (Pharmacist Name) ____/____/____ (Date/Time)



Instruct patients/caregivers to call the prescriber if:

- Patient is pregnant or plans to become pregnant. It is not known if XYWAV/XYREM can affect an unborn baby.
- Patient is breastfeeding. XYWAV/XYREM passes into breast milk. The patient/caregiver should talk to the prescriber to decide if the patient will take XYWAV/XYREM or breastfeed.
- Patient has or has had depression or tried to harm him- or herself. Patients should be watched for new signs of depression.
- Patient has liver problems. The dose may need to be adjusted.
- Patient has sleep apnea (short periods of not breathing while asleep), snoring, or breathing or lung problems. Patients with these may have a higher chance of serious breathing problems with XYWAV/XYREM.
- Patient has mental health problems.
- Patient walks during sleep.
- For patients taking XYREM: Patient is on a salt-restricted diet, has high blood pressure, heart failure, or kidney problems. XYREM is a drug with a high sodium (salt) content and may not be right for patients with these conditions.

_____ (Pharmacist Name) ____/____/____ (Date/Time)

For situations involving a change of care responsibility:

- Inform caregiver/patient that this completes this section of the checklist. Confirm that the caregiver/patient has asked any questions he or she has about XYWAV/XYREM.

STEP 3: SCREENING

(Complete this section for new patients, existing patients who are restarting XYWAV or XYREM treatment after not receiving either of the drug products for 6 months or longer, and patients who report a new medication or new comorbid medical condition listed in Step 4 of this checklist)

1. Is the patient taking sedative hypnotics (e.g., diazepam, phenobarbital, or zolpidem)?

- Yes Counseled Patient/Caregiver
- No

Please list the drug(s) and dose of each: _____

2. Is the patient taking sedating antidepressants, antipsychotics, or anti-epileptics such as divalproex sodium (Depakote); general anesthetics; muscle relaxants; opioid analgesics; or illicit CNS depressants (e.g., heroin or gamma-hydroxybutyrate [GHB])?

- Yes Counseled Patient/Caregiver
- No

Please list the drug(s) and dose of each: _____



3. What other prescription and non-prescription medications is the patient taking?

Please list the drug(s) and dose of each: _____

4. Does the patient drink alcohol?

- Yes Counseled Patient/Caregiver
- No

5. Has the patient been diagnosed with sleep apnea (short periods of not breathing while asleep)?

- Yes Counseled Patient/Caregiver
- No

6. Does the patient have a diagnosis of or suffer from asthma, chronic obstructive pulmonary disease (COPD), or other conditions affecting his/her breathing (slower breathing, trouble breathing)?

- Yes Counseled Patient/Caregiver
- No

Please list the drug(s) used to treat, and dose of each, if known:

7. Does the patient have any other current medical conditions for which the patient is under a healthcare provider's care?

- Yes Counseled Patient/Caregiver
- No

Please list the conditions(s) if known: _____

8. Does the patient/caregiver have any clinical questions about XYWAV and/or XYREM?

- Yes Counseled Patient/Caregiver
- No Referred Patient/Caregiver to Prescriber

Please list the question(s): _____

_____ (Pharmacist Name) _____ / _____ / _____ (Date/Time)



STEP 4: CONCOMITANT MEDICATION & COMORBIDITY SUMMARY

(Complete this section for new patients, existing patients who are restarting XYWAV or XYREM treatment after not receiving either of the drug products for 6 months or longer, and patients who report a new medication or new comorbid medical condition listed in Step 4 of this checklist)

Medication Type

- Sedative hypnotics
- Alcohol
- Other potentially interacting agents:
 - Sedating antidepressants, antipsychotics, or anti-epileptics
 - General anesthetics
 - Muscle relaxants
 - Opioid analgesics
 - Divalproex sodium or other valproate drug (e.g., valproic acid)
 - Illicit CNS depressants (e.g., heroin or gamma-hydroxybutyrate [GHB])

Medical Conditions

- Sleep apnea
- Asthma
- COPD
- Other conditions affecting the patient's breathing
- History of depression or suicidality
- History of drug or alcohol abuse
- Seizure disorders
- Hepatic impairment
- High blood pressure, heart problems, kidney problems, or a salt-restricted diet [Prescriber consult may be required for patients taking XYREM]

If any medication types or medical conditions listed above are checked, or any questions in Step 3 were answered yes and there is no confirmation of prior prescriber knowledge, call the prescriber to consult:

Is a prescriber consult required?

- Yes
- No

If no, please provide reason: _____

If yes, action(s) taken (check all that apply and document details in prescriber consult outcome section below):

- Called prescriber: ____/____/_____
- Other: ____/____/_____

Prescriber consult outcome: _____

_____ (Pharmacist Name) ____/____/_____ (Date/Time)



STEP 5: COMPLETION SUMMARY

(Complete this section for new patients, existing patients who are restarting XYWAV or XYREM treatment after not receiving either of the drug products for 6 months, and patients who report a new medication or new comorbid medical condition listed in Step 4 of this checklist)

Checklist Completed

- Yes
- No (XYWAV or XYREM is not shipped until checklist is completed.)

If yes, date checklist completed: ____/____/____ (Date Time)

If no, reason for non-completion: _____

_____ (Pharmacist Name) ____/____/____ (Date/Time)