



## **XYREM REMS PROGRAM PATIENT COUNSELING CHECKLIST**

***(To be completed by the pharmacist and entered in the XYREM REMS Program Central Database prior to dispensing each XYREM shipment. 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**

***(Complete this section for new patients [first shipment of XYREM], existing patients who are restarting XYREM treatment after not receiving XYREM for 6 months or longer, and patients who report any change in medication and/or medical history)***

- New/restart
- Scheduled refill
- Early refill approved through RMR process

Patient Name: \_\_\_\_\_ Patient ID Number: \_\_\_\_\_

Prescriber Name: \_\_\_\_\_ Prescriber 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 XYREM treatment after not receiving XYREM for 6 months or longer)***

- Verify that the patient will receive the XYREM REMS Program Patient Quick Start Guide (if not already received) and that the drug shipment to the patient will include the XYREM Medication Guide

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- Verify that patient has been counseled on **Therapy Expectations** below
  - During clinical trials with XYREM, many patients with narcolepsy saw some improvement with excessive daytime sleepiness and/or cataplexy in the first weeks after beginning XYREM therapy. However, the response to XYREM varies from patient to patient. It may also take time to find the right dose that works for you. Your doctor will determine the dose that is appropriate for you.
  - Be sure to talk to your doctor about any troubling side effects or if you don't feel any benefits while taking XYREM.
  - For any changes to your prescription, have your doctor call or fax the new prescription change to the pharmacy and NEVER attempt to change the dose yourself.

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- Verify that patient has been counseled on **Preparation and Administration** information below
  - XYREM should be taken as directed by your doctor (review prescriber’s instructions with patient).
    - Prepare each of your doses by placing \_\_\_ grams of XYREM in one of the provided pharmacy containers and place \_\_\_ grams in the second container. Add 1/4 cup of water to each pharmacy container. The water does not come with XYREM. You can use either tap or bottled water. The solution should remain clear and it will taste salty. Place the child-resistant cap onto the containers and put them in a safe place, out of the reach of children or pets, by your bed.
  - Feel free to call the XYREM REMS Program if you have any questions regarding preparation or how to take your XYREM doses. We are 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.
  - Refer to the Medication Guide for additional information on preparation of your XYREM doses.
  - Set alarm to go off 2.5 to 4 hours after you take your first dose.
  - When you are ready to go to sleep, sit at your bedside and drink one dose of XYREM and then lie down.
    - Your first dose of XYREM should be taken at least 2 hours after eating as food will decrease the amount of XYREM that your body absorbs.
    - Patients usually fall asleep 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 time that it takes to fall asleep might be different from night to night.
    - Upon waking up, take the second dose of medication as prescribed by your physician.
    - A minimum of 2.5 hours must separate each dose.
    - If you happen to miss a dose, NEVER take two doses of XYREM at once.
  - The diluted medication MUST be used within 24 hours of preparation. Discard any unused medication down the sink drain or toilet.
  - When you can no longer draw medication out of the bottle with the dispensing device, dispose of your bottle. Use a marker or pen to deface the bottle to protect your confidentiality.
  - Be sure to store XYREM in the original bottle in a safe and secure place out of the reach of children and pets. Get emergency help (call 911) right away if a child drinks your XYREM.
  - XYREM should be stored at room temperature.

\_\_\_\_\_ (Pharmacist Name)

\_\_\_/\_\_\_/\_\_\_ (Date Time)



- Verify that patient has been counseled on **Precautions needed for XYREM use:**
  - XYREM is classified as a controlled substance medication. 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.
  - The active ingredient in XYREM is sodium oxybate. Sodium oxybate is converted to gamma-hydroxybutyrate (GHB) in the body. 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 CNS depressants (for example nortriptyline, oxycodone, or heroin) including alcohol can lead to seizure, trouble breathing, decreases in the level of consciousness, coma, and death.
  - Tell your doctor if you:
    - Are pregnant or plan to become pregnant. It is not known if XYREM can affect your unborn baby.
    - Are breastfeeding. It is not known whether XYREM can pass through the breast milk. Talk to your doctor about the best way to feed your baby if you take XYREM.
    - Have or had depression or tried to harm yourself. You should be watched for new signs of depression.
    - Have liver problems. Your dose may need to be adjusted.
    - Have sleep apnea (short periods of not breathing while you sleep), snoring, or breathing or lung problems. You may have a higher chance of serious breathing problems with XYREM.
    - Have mental health problems.
    - Walk in your sleep.
    - Are on a salt-restricted diet, have high blood pressure, heart failure, or kidney problems. XYREM contains sodium (salt) and may not be right for you.

\_\_\_\_\_ (Pharmacist Name)

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Verify that patient has been counseled on Side Effects

- In clinical trials, the most commonly observed side effects associated with the use of XYREM included: headache, nausea, dizziness, sleepiness, vomiting, urinary incontinence, and inflammation of the area around the nostrils and the back of the mouth. Some side effects may be more likely to be observed with higher doses of XYREM.
- XYREM can cause serious side effects, including trouble breathing while asleep, confusion, unusual or disturbing thoughts, depression, and passing out, even at recommended doses. Tell your doctor if you have any of these problems while taking XYREM.
- Remember that you must not drive a car, operate heavy machinery, or perform any activity that is dangerous or that requires mental alertness or motor coordination for the first 6 hours after taking a dose of XYREM.
- When taking XYREM, do not drink alcohol or take medicines that make you sleepy, including antidepressants, antipsychotics, anti-epileptics, opioids, general anesthetics, muscle relaxants and/or illicit CNS depressants (for example, heroin or GHB).
- These are not all of the side effects that you might experience. Contact your doctor if you are concerned about any possible side effects. *Refer to the Medication Guide for additional information on possible side effects.*

\_\_\_\_\_ (Pharmacist Name)

\_\_\_/\_\_\_/\_\_\_ (Date Time)



### Step 3: Screening

*(Complete this section for new patients, existing patients who are restarting XYREM treatment after not receiving XYREM for 6 months or longer, and patients who report any change in medication and/or medical history)*

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

- Yes     Counseled Patient  
 No

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

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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 (for example, heroin or gamma-hydroxybutyrate [GHB])?

- Yes     Counseled Patient  
 No

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

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

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

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4. Does the patient drink alcohol?

- Yes     Counseled Patient  
 No

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

- Yes     Counseled Patient  
 No



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

- Yes     Counseled Patient
- No

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

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

- Yes     Counseled Patient
- No

Please list the condition(s) if known:

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8. Does the patient have any clinical questions about XYREM?

- Yes     Counseled Patient
- Referred patient to prescriber
- No

Please list the question(s):

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\_\_\_\_\_ (Pharmacist Name)

\_\_\_/\_\_\_/\_\_\_ (Date Time)



### Step 4: Concomitant Medication & Comorbidity Summary

*(Complete this section for new patients, existing patients who are restarting XYREM treatment after not receiving XYREM for 6 months or longer, and patients who report any change in medication and/or medical history)*

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 their breathing
- History of depression or suicidality
- History of drug or alcohol abuse
- Seizure disorders
- Hepatic impairment
- High blood pressure, heart problems, kidney problems, or are on a salt-restricted diet

*If any of the medication types or medical conditions listed above are checked, or any of the questions in Section 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 XYREM treatment after not receiving XYREM for 6 months, and patients who report any change in medication and/or medical history)*

Checklist Completed  Yes  No (XYREM is not shipped until checklist is completed.)

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

If no, reason for non-completion:

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\_\_\_\_\_ (Pharmacist Name)      \_\_/\_\_/\_\_\_\_ (Date Time)