



Pharmacy Staff Information

Name: _____

Job Title: _____

Knowledge Assessment: Module A

XYWAV and XYREM REMS Overview

1. XYWAV™ (calcium, magnesium potassium, and sodium oxybates) oral solution, 0.5 g/mL, and XYREM® (sodium oxybate) oral solution, 0.5 g/mL, are indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.
 - A. True
 - B. False(Answer: A)
2. Both XYWAV and XYREM contain GHB, and are controlled substances because:
 - A. It must be administered twice nightly
 - B. It has abuse potential
 - C. It requires dilution before dosing
 - D. It is a central nervous system (CNS) depressant(Answer: B)
3. XYWAV and XYREM are contraindicated in patients:
 - A. Who take sedative hypnotics
 - B. Who drink alcohol while using XYWAV or XYREM
 - C. Who have succinic semialdehyde dehydrogenase deficiency, a rare disorder of inborn error of metabolism variably characterized by mental retardation, hypotonia, and ataxia
 - D. A, B, and C(Answer: D)
4. XYWAV and XYREM are CNS depressants. Which of the following is NOT a warning related to CNS depression?
 - A. Concurrent use with other CNS depressants may increase the risk of respiratory depression, hypotension, profound sedation, syncope, and death
 - B. Patients who have sleep apnea or compromised respiratory function may be at a higher risk of developing respiratory depression, loss of consciousness, coma, and death with XYWAV or XYREM use
 - C. All surgeries and procedures must be reported as adverse events
 - D. Healthcare providers should caution patients/caregivers against hazardous activities requiring complete mental alertness or motor coordination (e.g., driving) within the first 6 hours of dosing or after first initiating treatment until certain that XYWAV or XYREM do not affect the patient adversely(Answer: C)



5. The XYWAV and XYREM REMS has which of the following requirements?
- A. Use of the central Certified Pharmacy
 - B. Healthcare providers who prescribe XYWAV or XYREM must have completed the XYWAV and XYREM REMS Prescriber Enrollment Form and must comply with the requirements of the XYWAV and XYREM REMS
 - C. For adult patients to receive XYWAV or XYREM, they must be enrolled in the XYWAV and XYREM REMS and be counseled on the serious risks and safe use of XYWAV and XYREM treatment
 - D. For pediatric patients to receive XYWAV or XYREM, they must be enrolled in the XYWAV and XYREM REMS and their caregiver must be counseled on the serious risks and safe use of XYWAV and XYREM
 - E. All of the above

(Answer: E)

6. In processing enrollment information, the XYWAV and XYREM REMS requires all of the following EXCEPT:
- A. The Certified Pharmacy will confirm that the prescriber's DEA, state license, and NPI numbers are active and that the prescriber has provided all REMS-related attestations
 - B. Prescribers are notified when they are enrolled in the XYWAV and XYREM REMS and can prescribe XYWAV and XYREM
 - C. When a patient enrollment form is received, the Central Database is searched to determine if a patient is already enrolled (duplicate patient)
 - D. The Certified Pharmacy will ensure that refill orders are shipped when a patient has approximately 10 days of therapy remaining from the previous shipment
 - E. A patient or prescriber may be disenrolled for noncompliance with the XYWAV and XYREM REMS

(Answer: D)

7. Which of the following is NOT true of caregivers of pediatric patients within the XYWAV and XYREM REMS?
- A. A caregiver for a pediatric patient can be changed
 - B. They must complete a separate enrollment form
 - C. They must sign the patient enrollment form attesting that they have been counseled
 - D. They must be counseled on the serious risks and safe use of XYWAV and XYREM

(Answer: B)

8. Which of the following is NOT entered in the Central Database in the XYWAV and XYREM REMS?
- A. Patient and prescriber enrollment information
 - B. Patient medical history
 - C. Interactions with patients, caregivers and prescribers
 - D. Prescription information
 - E. Shipment information
 - F. All of the above are entered

(Answer: F)



9. In validating a prescription for XYWAV or XYREM, the Certified Pharmacy will verify that:
- The XYWAV Prescription Form or the XYREM Prescription Form was received from the prescriber's office, is complete and signed by the prescriber, and is dated within the last 6 months;
 - The prescriber is enrolled in the XYWAV and XYREM REMS and has active DEA, state license, and NPI numbers;
 - The patient is enrolled in the XYWAV and XYREM REMS and has no other active XYWAV or XYREM prescriptions;
 - The prescription is for only a one-month supply (first fill) or no more than a 3-month supply (refills).
- A. True
B. False

(Answer: A)

10. When must a healthcare provider complete and submit a XYWAV Prescription Form to the pharmacy (select all that apply)?
- A. For a patient's initial prescription of XYWAV
 - B. For patients who are restarting XYWAV after a lapse in therapy of 6-months or longer
 - C. For all refills and renewals of XYWAV
 - D. If a patient changes from XYREM to XYWAV and has never had a previous prescription for XYWAV

(Answer: A, B and D)

11. In monitoring patients and prescribers for signs of inappropriate prescribing, abuse, misuse, and diversion, the pharmacy will:
- A. Document early refill requests and instances of patient and prescriber behavior that suggest potential abuse, misuse, or diversion by completing a XYWAV and XYREM REMS Risk Management Report
 - B. Place an alert in the patient's profile within the Central Database for repeated reports of lost, stolen, destroyed, or spilled drug for review prior to shipping XYWAV or XYREM
 - C. Inform a XYWAV and XYREM REMS pharmacist immediately if pharmacy staff suspects a patient or prescriber of abuse, misuse, or diversion
 - D. A and B only
 - E. A, B, and C

(Answer: E)

12. All potential adverse events must be reported to Jazz Pharmaceuticals within one business day.
- A. True
 - B. False

(Answer: A)