Knowledge Assessment: Module A

XYREM REMS Program Overview

1. XYREM® (sodium oxybate) oral solution, 0.5 g/mL, is 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. GHB, the active ingredient in XYREM, is a controlled substance 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. XYREM is contraindicated in patients:
   A. Who take sedative hypnotics
   B. Who drink alcohol while using 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. XYREM is a CNS depressant. 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 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 XYREM does not affect the patient adversely
   (Answer: C)

Reference ID: 4341394
5. The XYREM REMS Program has which of the following requirements?  
   A. Use of the central Certified Pharmacy  
   B. Healthcare providers who prescribe XYREM must have completed the XYREM REMS Program Prescriber Enrollment Form and must comply with the requirements of the XYREM REMS Program  
   C. For adult patients to receive XYREM, they must be enrolled in the XYREM REMS Program and be counseled on the serious risks and safe use of XYREM treatment  
   D. For pediatric patients to receive XYREM, they must be enrolled in the XYREM REMS Program and their caregiver must be counseled on the serious risks and safe use of XYREM  
   E. All of the above  
   (Answer: E)

6. In processing enrollment information, the XYREM REMS Program 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 XYREM REMS Program and can prescribe 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 XYREM REMS Program  
   (Answer: D)

7. Which of the following is NOT true of caregivers of pediatric patients within the XYREM REMS Program?  
   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 XYREM  
   (Answer: B)

8. Which of the following is NOT entered in the Central Database in the XYREM REMS Program?  
   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 XYREM, the Certified Pharmacy will verify that:
   • The XYREM REMS Program 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 XYREM REMS Program and has active DEA, state license, and NPI numbers;
   • The patient is enrolled in the XYREM REMS Program and has no other active XYREM prescriptions; and
   • 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. 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 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 XYREM
   C. Inform a XYREM REMS Program 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)

11. All potential adverse events must be reported to Jazz Pharmaceuticals within one business day.
   A. True
   B. False
   (Answer: A)