OPTUMRx®

Sesquient™ (fosphenytoin sodium) – New drug approval

- On November 9, 2020, Sedor Pharmaceuticals announced the FDA approval of Sesquient (fosphenytoin sodium), for the:

  — Treatment of generalized tonic-clonic status epilepticus in adult patients
  — Prevention and treatment of seizures occurring during neurosurgery in adult patients
  — Short-term substitution for oral phenytoin in patients 2 years of age and older. Sesquient should be used only when oral phenytoin administration is not possible.

- Another fosphenytoin sodium injectable formulation is available generically with similar indications as Sesquient. However, Sesquient is the only FDA-approved room-temperature stable formulation of fosphenytoin sodium.

- The efficacy of Sesquient is based upon bioavailability studies comparing Sesquient to another IV fosphenytoin that does not contain betadex sulfobutyl ether sodium. The content of betadex sulfobutyl ether sodium present in Sesquient limits use in the pediatric population to non-urgent loading dosing and short-term maintenance dosing as replacement for oral phenytoin in patients older than 2 years.

- Sesquient carries a boxed warning for cardiovascular risk associated with rapid infusion rates.

- Sesquient is contraindicated in patients with:

  — A history of hypersensitivity to fosphenytoin, phenytoin, other hydantoins, or any of the inactive ingredients in Sesquient
  — Sinus bradycardia, sino-atrial block, second and third degree A-V block, or Adams-Stokes syndrome because of the effect of parenteral phenytoin or Sesquient on ventricular automaticity
  — A history of prior acute hepatotoxicity attributable to Sesquient, fosphenytoin, or phenytoin
  — Coadministration with delavirdine because of the potential for loss of virologic response and possible resistance to delavirdine or to the class of non-nucleoside reverse transcriptase inhibitors.

- Additional warnings and precautions for Sesquient include dosing errors; withdrawal precipitated seizure, status epilepticus; serious dermatologic reactions; drug reaction with eosinophilia and systemic symptoms (DRESS)/multiorgan hypersensitivity; hypersensitivity; angioedema; hepatic injury; hematopoietic complications; sensory disturbances; local toxicity (including purple glove syndrome); phosphate load; renal or hepatic disease or hypoalbuminemia; exacerbation of porphyria; teratogenicity and other harm to the newborn; hyperglycemia; and serum phenytoin levels above therapeutic range.

- The most common adverse reactions (10%) with Sesquient use were:

  — Adults: pruritus, nystagmus, dizziness, somnolence, and ataxia
  — Pediatrics: vomiting, nystagmus, and ataxia.

- The recommended loading dose for Sesquient for status epilepticus in adults is 15 mg phenytoin sodium equivalents (PE)/kg to 20 mg PE/kg at an intravenous (IV) infusion rate of 100 mg PE/min to 150 mg PE/min.

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- The non-emergent loading and maintenance dosing for Sesquient are as follows:

  — Adult loading dose is 10 mg PE/kg to 20 mg PE/kg given IV; initial maintenance dose is 4 mg PE/kg to 6 mg PE/kg/day in divided doses
  — Pediatric loading dose is 10 mg PE/kg to 15 mg PE/kg given IV; initial maintenance dose is 2 mg PE/kg to 4 mg PE/kg every 12 hours. Because of the betadex sulfobutyl ether sodium ingredient in Sesquient, administration rate in pediatric patients should not exceed 0.4 mg PE/kg/min. The rate of administration of IV Sesquient in pediatric patients differs from that of other IV fosphenytoin products.

- Sedor Pharmaceuticals' launch plans for Sesquient are pending. Sesquient injection will be available as:

  — 500 mg PE per 10 mL (50 mg PE/mL) in single-dose vials
  — 100 mg PE per 2 mL (50 mg PE/mL) in single-dose vials.

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