Summary of prescribing information for FOSPHEN injection

Active Ingredient: each ml of FOSPHEN injection contains: fosphenytoin sodium USP 75 mg equivalent to phenytoin 50 mg; 2 ml and 10 ml vial. **Indication:** Generalized convulsive status epilepticus, prevention & treatment of seizures occurring during neurosurgery & head injury when other means of phenytoin administration are unavailable, inappropriate or less advantageous. **Dosage:** dose, concentration, and infusion rate of fosphenytoin should always be expressed as phenytoin sodium equivalents (PE). For Status Epilepticus: Adult loading dose is 15 to 20 mg PE/kg at a rate of 100 to 150 mg PE/min; Pediatric loading dose is 15 to 20 mg PE/kg at a rate of 2 mg PE/kg/min (or 150 mg PE/min, whichever is slower). For Non-emergent Loading and Maintenance Dosing: Adult loading dose is 10 to 20 mg PE/kg given IV or IM; initial maintenance dose is 4 to 6 mg PE/kg/day in divided doses; Pediatric loading dose is 10 to 15 mg PE/kg at a rate of 1 to 2 mg PE/kg/min (or 150 mg PE/min, whichever is slower); initial maintenance dose is 2 to 4 mg PE/kg every 12 hours at a rate of 1 to 2 mg PE/kg/min (or 100 mg PE/min, whichever is slower). Intramuscular Administration: should ordinarily not be given intramuscularly. **Contraindications:** Hypersensitivity to fosphenytoin, its ingredients, phenytoin, hydantoins. Sinus bradycardia, sino-atrial block, second and third degree A-V block, and Adams-Stokes syndrome. History of prior acute hepatotoxicity attributable to fosphenytoin or phenytoin. Coadministration with delavirdine. **Warning and precautions:** Dosing Errors: Do not confuse the amount of drug to be given in PE with the concentration of the drug in the vial. Ensure the appropriate volume is withdrawn from the vial when preparing for administration. Withdrawal Precipitated Seizure: May precipitate status epilepticus. Dose reductions or discontinuation should be done gradually. Serious Dermatologic Reactions: Discontinue at the first sign of a rash, unless clearly not drug-related. If signs or symptoms suggest SJS/TEN, should not be resumed; consider alternative therapy. Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan Hypersensitivity: If signs or symptoms of hypersensitivity are present, evaluate the patient immediately. Discontinue if an alternative etiology cannot be established. Angioedema: Discontinue immediately if symptoms of angioedema such as facial, perioral, or upper airway swelling occur. Hematopoietic Complications: If occurs, follow-up observation is indicated and an alternative antiepileptic treatment should be used. **Pregnancy & Lactation:** Pregnancy: Phenytoin (the active metabolite of fosphenytoin) prenatal exposure may increase risks for congenital malformations and other adverse developmental outcomes. Lactation: It is not known whether fosphenytoin is secreted in human milk. **Interaction:** Multiple drug interactions because of extensive plasma protein binding, saturable metabolism, and potent induction of hepatic enzymes. **Adverse reactions:** Most common, Adults: pruritus, nystagmus, dizziness, somnolence, and ataxia. Pediatrics: vomiting, nystagmus, and ataxia. **Overdose:** Nausea, vomiting, lethargy, tachycardia, bradycardia, asystole, cardiac arrest, hypotension, syncope, hypocalcemia, metabolic acidosis, and death have been reported in cases of overdosage with fosphenytoin. Because fosphenytoin is a prodrug of phenytoin, the following information about phenytoin overdosage may be helpful. Initial symptoms of acute phenytoin toxicity are nystagmus, ataxia, and dysarthria. Other signs include tremor, hyperreflexia, lethargy, slurred speech, nausea, vomiting, coma, and hypotension. Depression of respiratory and circulatory system leads to death. Treatment is nonspecific since there is no known antidote to fosphenytoin or phenytoin. The adequacy of the respiratory and circulatory systems should be carefully observed, and appropriate supportive measures employed. Hemodialysis can be considered since phenytoin (the active metabolite of fosphenytoin) is not completely bound to plasma proteins. Total exchange transfusion has been used in the treatment of severe intoxication in children.

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It is recommended to refer full prescribing information before prescription.

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