Cerebyx® (fosphenytoin) – Expanded indication

- On March 1, 2017, the FDA approved Pfizer's Cerebyx (fosphenytoin) injection for the treatment of generalized tonic-clonic status epilepticus and prevention and treatment of seizures occurring during neurosurgery in pediatric patients from birth to < 17 years of age.
    - Previously, Cerebyx was only approved for use in adults.
    - Cerebyx can also be substituted, short-term, for oral phenytoin. Cerebyx should be used only when oral phenytoin administration is not possible.
- Cerebyx carries a boxed warning for cardiovascular risk associated with rapid infusion rates.
- The Cerebyx drug label was updated with a new addition to the *Contraindication* section regarding a history of prior acute hepatotoxicity attributable to Cerebyx or phenytoin.
- The most common adverse reactions (≥ 10%) with Cerebyx use in pediatric patients were vomiting, nystagmus and ataxia.
- The recommended intravenous (IV) doses of Cerebyx for adult and pediatric patients are as follows:

Indication	Patient Population	Dose
Status Epilepticus	Pediatrics	15 to 20 mg PE/kg at a rate of 2 mg PE/kg/min (or 150 mg PE/min, whichever is slower)
	Adults	15 to 20 mg PE/kg at a rate of 100 to 150 mg PE/min
Non-Emergent Use	Pediatrics	*Loading dose:* 10 to 15 mg PE/kg at a rate of 1 to 2 mg PE/kg/min *Initial maintenance dose:* 2 to 4 mg PE/kg every 12 hours at a rate of 1 to 2 mg PE/kg/min (no faster than 100 mg PE/min)
	Adults	*Loading dose:* 10 to 20 mg PE/kg given IV or intramuscular(IM) *Initial maintenance dose:* 4 to 6 mg PE/kg/day in divided doses

PE: phenytoin sodium equivalents

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- Because of the risks of cardiac and local toxicity associated with IV Cerebyx, oral phenytoin should be used whenever possible for non-emergent use.

- IM administration of Cerebyx should ordinarily not be used.