

## 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
<b>Status Epilepticus</b>	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
<b>Non-Emergent Use</b>	Pediatrics	<i>Loading dose:</i> 10 to 15 mg PE/kg at a rate of 1 to 2 mg PE/kg/min  <i>Initial maintenance dose:</i> 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	<i>Loading dose:</i> 10 to 20 mg PE/kg given IV or intramuscular(IM)  <i>Initial maintenance dose:</i> 4 to 6 mg PE/kg/day in divided doses

PE: phenytoin sodium equivalents

- 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.



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