

IMPORTANT PRESCRIBING INFORMATION

Dear Health Care Professional:

Re: **Cerebyx[®] (fosphenytoin sodium injection)**
Important vial and carton label change

Massive overdoses of Cerebyx associated with serious adverse events, including death, have resulted from health care workers' mistaken interpretation of the current vial label (both 2mL and 10mL vials). Specifically, some health care workers withdrawing Cerebyx from the vial have misinterpreted the vial label to mean that the amount of phenytoin equivalents per milliliter actually represents the total amount of phenytoin equivalents in the vial.

In response, Parke-Davis will be revising the vial and carton labels.

The revised packaging is designed to further reinforce the total amount of phenytoin equivalents (PE) in each Cerebyx vial.

The new vial labels will read as follows:

2mL vial: **Cerebyx**
 (Fosphenytoin Sodium Injection)
 100mg PE in 2mL
 (PE= phenytoin sodium equivalents)
 2mL vial

10mL vial: **Cerebyx**
 (Fosphenytoin Sodium Injection)
 500mg PE in 10mL
 (PE= phenytoin sodium equivalents)
 10mL vial

It is important to emphasize that all Cerebyx vials (both current and newly labeled product) contain the same 50mg PE/mL concentration. The above change serves to further highlight the total contents of each vial. It is important to realize that supplies of Cerebyx currently available will not have the revised label for several weeks. During this period staff should be particularly cautious when preparing Cerebyx for injection.

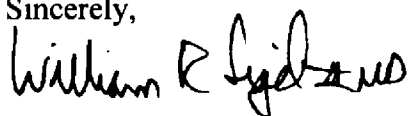
The revised labels will continue to express Cerebyx dosage in phenytoin sodium equivalents (PE). By using phenytoin sodium equivalents (PE), physicians will not have to make dosing adjustments when converting from phenytoin sodium to Cerebyx or vice versa. For example, in a situation where a physician prescribes a 1000mg dose of IV phenytoin sodium, a 1000mg PE dose of Cerebyx would be the therapeutic equivalent. Cerebyx should always be prescribed and dispensed in phenytoin sodium equivalents (PE).

Please continue to ensure that pharmacy staff, emergency room personnel, nurses and other medical staff understand the total contents of each Cerebyx vial, and that Cerebyx is dosed in phenytoin sodium equivalents (PE).

Cerebyx (fosphenytoin sodium injection) is a parenteral phenytoin therapy indicated for the control of generalized convulsive status epilepticus, the prevention and treatment of seizures occurring during neurosurgery, and as a short-term substitute for oral phenytoin. Cerebyx is a water-soluble prodrug that rapidly and completely converts to phenytoin following injection or infusion.

If you have any questions about Cerebyx or the contents of this letter, please call our toll-free number: 1-800-223-0432.

Sincerely,



William Sigmund II, MD
Vice President
Medical and Scientific Affairs

Please see enclosed full prescribing information.

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