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PRESS RELEASE

FOR IMMEDIATE RELEASE

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American Regent Announces the Availability of Fosphenytoin Sodium Injection, USP

Shirley, NY – (October 26, 2010): American Regent, Inc. is pleased to announce the availability of Fosphenytoin Sodium Injection, USP.

Product	Strength	NDC Number	Shelf Pack
Fosphenytoin Sodium Injection, USP	75 mg/mL (50 mg PE/mL) (PE = phenytoin sodium equivalent), 2 mL Vial	00517-6902-25	25

Fosphenytoin Sodium Injection, USP is “AP” Rated to Cerebyx® (fosphenytoin sodium injection, USP, a product of PFIZER) and is Latex and Preservative Free.

Headquartered in Shirley, NY, American Regent, Inc., distributes over 80 pharmaceutical products under the PharmaForce or their own label, including Venofer® (iron sucrose injection, USP), the #1 selling IV iron therapy in the U.S. For more information about this product or other American Regent or PharmaForce products, please contact our customer service department at 1-800-645-1706.

Source: American Regent, Inc.

See accompanying Important Safety Information and Full Prescribing Information

IMPORTANT SAFETY INFORMATION

FOSPHENYTOIN SODIUM INJECTION, USP

IMPORTANT SAFETY INFORMATION: Fosphenytoin sodium is contraindicated in patients who have demonstrated hypersensitivity to fosphenytoin sodium or its ingredients, or to phenytoin or other hydantoin. Because of the effect of parenteral phenytoin on ventricular automaticity, fosphenytoin sodium is contraindicated in patients with sinus bradycardia, sino-atrial block, second and third degree AV block, and Adams-Stokes syndrome.

DOSES OF FOSPHENYTOIN SODIUM ARE EXPRESSED AS THEIR PHENYTOIN SODIUM EQUIVALENTS (PE=phenytoin sodium equivalent). DO NOT, THEREFORE, MAKE ANY ADJUSTMENT IN THE RECOMMENDED DOSES WHEN SUBSTITUTING FOSPHENYTOIN SODIUM FOR PHENYTOIN SODIUM OR VICE VERSA.

Antiepileptic drugs should not be abruptly discontinued because of the possibility of increased seizure frequency, including status epilepticus. When, in the judgment of the clinician, the need for dosage reduction, discontinuation, or substitution of alternative antiepileptic medication arises, this should be done gradually.

Hypotension may occur, especially after IV administration at high doses and high rates of administration. Following administration of phenytoin, severe cardiovascular reactions and fatalities have been reported with atrial and ventricular conduction depression and ventricular fibrillation. Severe complications are most commonly encountered in elderly or gravely ill patients. Therefore, careful cardiac monitoring is needed when administering IV loading doses of fosphenytoin sodium. Reduction in rate of administration or discontinuation of dosing may be needed. Fosphenytoin sodium should be used with caution in patients with hypotension and severe myocardial insufficiency.

Fosphenytoin sodium should be discontinued if a skin rash appears. If the rash is exfoliative, purpuric, or bullous, or if lupus erythematosus, Stevens-Johnson syndrome, or toxic epidermal necrolysis is suspected, use of this drug should not be resumed and alternative therapy should be considered.

Cases of acute hepatotoxicity, including infrequent cases of acute hepatic failure, have been reported with phenytoin. These incidents have been associated with a hypersensitivity syndrome characterized by fever, skin eruptions, and lymphadenopathy, and usually occur within the first 2 months of treatment. The clinical course of acute phenytoin hepatotoxicity ranges from prompt recovery to fatal outcomes. In these patients with acute hepatotoxicity, fosphenytoin sodium should be immediately discontinued and not readministered.

Hemopoietic complications, some fatal, have occasionally been reported in association with administration of phenytoin. These have included thrombocytopenia, leukopenia, granulocytopenia, agranulocytosis, and pancytopenia with or without bone marrow suppression.

There have been a number of reports that have suggested a relationship between phenytoin and the development of lymphadenopathy (local or generalized), including benign lymph node hyperplasia, pseudolymphoma, lymphoma, and Hodgkin's disease.

An increase in seizure frequency may occur during pregnancy because of altered phenytoin pharmacokinetics. Periodic measurement of plasma phenytoin concentrations may be valuable in the

management of pregnant women as a guide to appropriate adjustment of dosage. If this drug is used during pregnancy, or if the patient becomes pregnant while taking the drug, the patient should be apprised of the potential harm to the fetus. Prenatal exposure to phenytoin may increase the risks for congenital malformations and other adverse developmental outcomes. Increased frequencies of major malformations (such as orofacial clefts and cardiac defects), minor anomalies (dysmorphic facial features, nail and digit hypoplasia), growth abnormalities (including microcephaly), and mental deficiency have been reported among children born to epileptic women who took phenytoin alone or in combination with other antiepileptic drugs during pregnancy. Patients should consult with their physicians to weigh the risks and benefits of phenytoin during pregnancy.

Drugs highly bound to albumin could increase the unbound fraction of fosphenytoin. Although it is unknown whether this could result in clinically significant effects, caution is advised when administering fosphenytoin sodium with other drugs that significantly bind to serum albumin. The most significant drug interactions following administration of fosphenytoin sodium are expected to occur with drugs that interact with phenytoin. Phenytoin is extensively bound to serum plasma proteins and is prone to competitive displacement. Phenytoin is metabolized by hepatic cytochrome P450 enzymes and is particularly susceptible to inhibitory drug interactions because it is subject to saturable metabolism. Inhibition of metabolism may produce significant increases in circulating phenytoin concentrations and enhance the risk of drug toxicity. Phenytoin is a potent inducer of hepatic drug-metabolizing enzymes.

The more important adverse clinical events caused by the IV use of fosphenytoin sodium or phenytoin are cardiovascular collapse and/or central nervous system depression. Hypotension can occur when either drug is administered rapidly by the IV route. The rate of administration is very important; for fosphenytoin sodium, it should not exceed 150 mg PE/min. The adverse clinical events most commonly observed with the use of fosphenytoin sodium in clinical trials were nystagmus, dizziness, pruritus, paresthesia, headache, somnolence, and ataxia. With two exceptions, these events are commonly associated with the administration of IV phenytoin. Paresthesia and pruritus, however, were seen much more often following fosphenytoin sodium administration and occurred more often with IV fosphenytoin sodium administration than with IM fosphenytoin sodium administration.