Fosphenytoin Sodium Injection, USP

**DESCRIPTION**

Fosphenytoin sodium injection, USP 75 mg/mL is a white to off-white, slightly viscous, sterile, pyrogen-free solution for parenteral administration. Each mL contains fosphenytoin sodium equivalent to 50 mg phenytoin sodium. Each 1 mL vial offosphenytoin sodium injection contains 75 mg/mL fosphenytoin sodium (hereafter referred to as fosphenytoin) and 0.1 mg/mL of sodium metabisulfite. The molecular structure of fosphenytoin is:

**INDICATIONS AND USAGE**

Fosphenytoin sodium injection is indicated for the treatment of: 1) Status epilepticus in adult patients (see CLINICAL PHARMACOLOGY: Pharmacokinetics); 2) Hysterical seizures (porphyria prophylaxis) in patients at high risk for complications of acute porphyria (see PRECAUTIONS: Porphyrias); 3) Renal failure. Fosphenytoin sodium injection is also indicated for the treatment of status epilepticus in maternal-fetal unit (see CLINICAL PHARMACOLOGY: Pregnancy: Usage in Pregnancy). The use of fosphenytoin sodium injection for any indication other than that for which it has been approved is superseded by the use of fosphenytoin sodium injection in the treatment of status epilepticus in maternal-fetal unit.

**CONTRAINDICATIONS**

Fosphenytoin sodium injection is contraindicated in patients with known hypersensitivity to this product. Fosphenytoin sodium injection contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic reactions and life-threatening or less severe asthmatic episodes.

**WARNINGS**

**Porphyria**

Fosphenytoin sodium injection should not be administered in patients who have had acute porphyria attacks or who have a family history of porphyria. If a patient develops symptoms compatible with acute porphyria, fosphenytoin sodium injection should be discontinued and appropriate therapy initiated. The patient should be carefully observed for signs and symptoms of porphyric attacks. Because of the potential for exacerbation of acute porphyria attacks, fosphenytoin sodium injection should not be substituted for other anticonvulsants in patients who have had acute porphyria attacks or who have a family history of porphyria.

**Hypersensitivity Reactions**

Fosphenytoin sodium injection should not be administered in patients who have a history of anaphylactic reactions to other anticonvulsants or to other fosphenytoin products.

**Risk for Hypersensitivity**

Individuals who are allergic to any component of the product formulation should not receive fosphenytoin sodium injection.

**Precautions**

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**Usage in Pregnancy**

Fosphenytoin sodium injection should be used with caution in patients in whom the plasma drug concentrations are at risk of being potentially subtherapeutic or supratherapeutic. The decision to use fosphenytoin sodium injection during pregnancy requires consideration of maternal-fetal risks and benefits of anticonvulsant therapy. Several studies of small sample size have indicated that maternal-fetal unit outcomes are similar to those of phenytoin sodium injection. Fosphenytoin sodium injection is available in a concentration of 75 mg/mL. The drug should be given only by route of administration that provides for monitoring of plasma concentration and where appropriate, therapeutic drug monitoring.

**DOSAGES AND ADMINISTRATION**

**Dosage**

Fosphenytoin sodium injection is available in single-dose vials containing 75 mg/mL fosphenytoin sodium equivalent to 50 mg/mL phenytoin sodium. Each mL vial contains fosphenytoin sodium equivalent to 75 mg/mL fosphenytoin sodium and 0.1 mg/mL sodium metabisulfite. The molecular structure of fosphenytoin is:

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Phenytoin sodium injection (fosphenytoin sodium injection) is a prodrug of phenytoin sodium. Serologic methods are not sensitive enough to detect fosphenytoin in the serum. The minimum detectable level of fosphenytoin is approximately 0.5 micrograms per milliliter.

Phenytoin is primarily excreted in the urine. The elimination half-life of phenytoin is 24 hours for adults and 12 hours for children. Therapeutic plasma concentrations of total phenytoin are between 10 to 20 micrograms per milliliter. Peak plasma concentrations of total phenytoin are usually seen 1 to 3 hours following IV administration.

Treatment of Overdosage

In acute overdosage the possibility of other CNS depressants, including alcohol, should be borne in mind. The adequacy of the respiratory and circulatory systems should be carefully observed, and appropriate supportive measures should be taken. Phenobarbital is the treatment of choice for the management of acute phenytoin intoxication in the child, although diazepam may also be effective.

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