Fosphenytoin Sodium

CAS Number : 92134-98-0
Bioavailability : 100% (IM)
Protein binding : 95 to 99%
Molecular Weight : 406.24 g/mol
Molecular Formula : C16H15N2O6P
Systematic (IUPAC) : (2,5-dioxo-4,4-diphenyl-imidazolidin-1-yl)methoxyphosphonic acid
DESCRIPTION
Hydantoin anticonvulsants (hye-DAN-toyn an-tye-kon- VUL-sants) are used most often to control certain convulsions or seizures in the treatment of epilepsy. Phenytoin also may be used for other conditions as determined by your doctor. In seizure disorders, these medicines act on the central nervous system (CNS) to reduce the number and severity of seizures. Hydantoin anticonvulsants may also produce some unwanted effects. These depend on the patient's individual condition, the amount of medicine taken, and how long it has been taken. Thought to regulate neuronal membrane by promoting sodium excretion from neurons. This action prevents hyperexcitability and excessive stimulation, which inhibits spread of seizure activity. Lacks general CNS depressant effect. Used for the control of generalized convulsive status epilepticus and prevention and treatment of seizures occurring during neurosurgery; indicated for short-term parenteral administration when other means of phenytoin administration are unavailable, inappropriate or deemed less advantageous (the safety and effectiveness of fosphenytoin in this use has not been systematically evaluated for more than 5 days

DOSAGE
The dose, concentration in dosing solutions, and infusion rate of IV is expressed as phenytoin sodium equivalents (PE) to avoid the need to perform molecular weight-based adjustments when converting between fosphenytoin and phenytoin sodium doses. Should always be prescribed and dispensed in phenytoin
sodium equivalent units (PE) has important differences in administration from those for parenteral phenytoin sodium. The loading dose is 15 to 20 mg PE/kg administered at 100 to 150 mg PE/min. Because of the risk of hypotension, fosphenytoin should be administered no faster than 150 mg PE/min. Continuous monitoring of the electrocardiogram, blood pressure, and respiratory function is essential and the patient should be observed throughout the period where maximal serum phenytoin concentrations occur, approximately 10 to 20 minutes.

**SIDE EFFECTS**

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Side effects are similar to phenytoin, except that fosphenytoin causes less hypotension and more paresthesia. Fosphenytoin can cause hyperphosphatemia in end-stage renal failure patients.

More common

- Bleeding, tender, or enlarged gums (rare with ethotoin);
- burning, tingling, pain, or itching, especially in the groin—following fosphenytoin injection; clumsiness or unsteadiness; confusion; continuous, uncontrolled back-and-forth and/or rolling eye movements—may be sign of overdose;
- swollen glands in neck or underarms; fever;
- muscle pain; skin rash or itching; slurred speech or stuttering—may be sign of overdose;
- sore throat;
- trembling—may be sign of overdose;
- unusual excitement, nervousness, or irritability

Rare

- Bone malformations; burning pain at place of injection;
- chest discomfort; chills and fever; dark urine; dizziness;
- frequent breaking of bones; headache; joint pain;
learning difficulties—in children taking high doses for a long time; light gray-colored stools; loss of appetite; nausea or vomiting; pain of penis on erection; restlessness or agitation; slowed growth; stomach pain (severe); troubled or quick, shallow breathing; uncontrolled jerking or twisting movements of hands, arms, or legs; uncontrolled movements of lips, tongue, or cheeks; unusual bleeding (such as nosebleeds) or bruising; unusual tiredness or weakness; weight loss (unusual); yellow eyes or skin.

PRECAUTIONS
Do not start or stop taking any other medicine without your doctor's advice. Other medicines may affect the way this medicine works.
This medicine will add to the effects of alcohol and other CNS depressants (medicines that may make you drowsy or less alert). Some examples of CNS depressants are antihistamines or medicine for hay fever, other allergies, or colds; sedatives, tranquilizers, or sleeping medicine; prescription pain medicine or narcotics; barbiturates; other medicine for seizures; muscle relaxants; or anesthetics, including some dental anesthetics. Check with your doctor before taking any of the above while you are using this medicine.
Do not take this medicine within 2 to 3 hours of taking antacids or medicine for diarrhea. Taking these medicines and hydantoin anticonvulsants too close together may make the hydantoins less effective.
Do not change brands or dosage forms of phenytoin without first checking with your doctor. Different products may not work the same way. If you refill your
medicine and it looks different, check with your pharmacist.

If you have been taking this medicine regularly for several weeks or more, do not suddenly stop taking it. Your doctor may want you to reduce gradually the amount you are taking before stopping completely.

For diabetic patients:
This medicine may affect blood sugar levels. If you notice a change in the results of your blood or urine sugar tests or if you have any questions, check with your doctor.

Before you have any medical tests, tell the doctor in charge that you are taking this medicine. The results of some tests (including the dexamethasone, metyrapone, or Schilling tests, and certain thyroid function tests) may be affected by this medicine.

Before having any kind of surgery, dental treatment, or emergency treatment, tell the medical doctor or dentist in charge that you are taking this medicine. Taking hydantoin anticonvulsants together with medicines that are used during surgery or dental or emergency treatments may cause increased side effects.

This medicine may cause some people to become dizzy, lightheaded, drowsy, or less alert than they are normally. After you have taken this medicine for a while, this effect may not be so bothersome. However, make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are dizzy or are not alert.

Oral contraceptives (birth control pills) containing estrogen or progestin, contraceptive progestin injections (e.g., Depo-Provera), and implant contraceptive forms of progestin (e.g., Norplant) may not work properly if you take them while you are taking hydantoin.
anticonvulsants. Unplanned pregnancies may occur. You should use a different or additional means of birth control while you are taking hydantoin anticonvulsants. If you have any questions about this, check with your health care professional.

**INTERACTION**

**Drug-drug.** Amiodarone, benzodiazepines, chloramphenicol, cimetidine, disulfiram, estrogens, felbamate, fluconazole, fluoxetine, halothane, influenza vaccine, isoniazid, itraconazole, ketoconazole, methylphenidate, miconazole, omeprazole, phenothiazines, phenylbutazone, salicylates, sulfonamides, tolbutamide, trazodone: increased fosphenytoin blood level

Antidepressants, antihistamines, opioids, sedative-hypnotics: additive CNS depression

Barbiturates, carbamazepine, reserpine: decreased fosphenytoin blood level

Corticosteroids, cyclosporine, doxycycline, estrogens, felbamate, methadone, quinidine, rifampin: altered effects of these drugs

Dopamine: additive hypotension

Lidocaine, propranolol: additive cardiac depression

Streptozocin, theophylline: decreased efficacy of these drugs

Warfarin: initial increase in warfarin effects in patients stabilized on warfarin therapy, followed by decreased response to warfarin

**Drug-diagnostic tests.** Alkaline phosphatase, glucose, hepatic enzymes: increased levels

Dexamethasone, metyrapone: test interference

Glucose tolerance test: decreased tolerance
Potassium, thyroxine: decreased levels
Thyroid function tests: decreased values
Drug-behaviors. Acute alcohol ingestion: increased drug blood level, additive CNS depression
Chronic alcohol ingestion: decreased drug blood level

CONSUMER INFORMATION
For patients taking the liquid form of this medicine:
* Shake the bottle well before using.
* Use a specially marked measuring spoon, a plastic syringe, or a small measuring cup to measure each dose accurately. The average household teaspoon may not hold the right amount of liquid.
For patients taking the chewable tablet form of this medicine:
* Tablets may be chewed or crushed before they are swallowed, or may be swallowed whole.
For patients taking the capsule form of this medicine:
* Swallow the capsule whole.
If this medicine upsets your stomach, take it with food, unless otherwise directed by your doctor. The medicine should always be taken at the same time in relation to meals to make sure that it is absorbed in the same way.
To control your medical problem, take this medicine every day exactly as ordered by your doctor. Do not take more or less of it than your doctor ordered. To help you remember to take the medicine at the correct times, try to get into the habit of taking it at the same time each day.
Dosing—The dose of hydantoin anticonvulsants will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of ethotoin,
fos Fosphenytoin, me Fosphenytoin, and Fosphenytoin. If your dose is different, do not change it unless your doctor tells you to do so.

The number of capsules or tablets or teaspoonfuls of suspension that you take or the number of injections you receive depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using a hydantoin anticonvulsant.

* For ethotoin

* For oral dosage form (tablets):
  o As an anticonvulsant:
    Adults and teenagers—To start, 125 to 250 milligrams (mg) four to six times a day. Your doctor may increase your dose gradually over several days if needed. However, the dose is usually not more than 3000 mg a day.
    Children—To start, up to 750 mg a day, based on the age and weight of the child. The doctor may increase the dose gradually if needed.

* For fos Fosphenytoin

* For injection dosage form:
  As an anticonvulsant:

Adults and children—Dose is based on the illness being treated, and the body weight or size of the patient. The medicine is injected into a vein or muscle.

* For me Fosphenytoin

* For oral dosage form (tablets):
  As an anticonvulsant:

Adults and teenagers—To start, 50 to 100 milligrams (mg) once a day. Your doctor may increase your dose by 50 to 100 mg a day at weekly intervals if needed.
However, the dose is usually not more than 1200 mg a day.

Children—To start, 25 to 50 mg once a day. The doctor may increase the dose by 25 to 50 mg a day at weekly intervals if needed. However, the dose is usually not more than 400 mg a day.

* For Fosphenytoin

* For oral dosage forms (capsules, chewable tablets, or suspension):
  As an anticonvulsant:
  Adults and teenagers—To start, 100 to 125 milligrams (mg) three times a day. Your doctor may adjust your dose at intervals of seven to ten days if needed.
  Children—Dose is based on body weight or body surface area. The usual dose is 5 mg of Fosphenytoin per kilogram (kg) (2.3 mg per pound) of body weight to start. The doctor may adjust the dose if needed.
  Older adults—Dose is based on body weight. The usual dose is 3 mg per kg (1.4 mg per pound) of body weight. The doctor may need to adjust the dose based on your response to the medicine.

* For injection dosage form:
  As an anticonvulsant:
  Adults and children—Dose is based on the illness being treated, and the body weight or size of the patient. The medicine is usually injected into a vein.
  Missed dose—If you miss a dose of this medicine and your dosing schedule is:
  * One dose a day—Take the missed dose as soon as possible. However, if you do not remember the missed dose until the next day, skip it and go back to your regular dosing schedule. Do not double doses.
  * More than one dose a day—Take the missed dose as soon as possible. However, if it is within 4 hours of your
next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses. If you miss doses for 2 or more days in a row, check with your doctor.

Storage—To store this medicine:
* Keep out of the reach of children.
* Store away from heat and direct light.
* Do not store in the bathroom, near the kitchen sink, or in other damp places. Heat or moisture may cause the medicine to break down.
* Keep the liquid form of this medicine from freezing. Do not refrigerate.
* Do not keep outdated medicine or medicine no longer needed. Be sure any discarded medicine is out of the reach of children.

**DRUG DESCRIPTION**

Cerebyx® (fosphenytoin sodium injection) is a prodrug intended for parenteral administration; its active metabolite is phenytoin. Each Cerebyx vial contains 75 mg/mL fosphenytoin sodium (hereafter referred to as fosphenytoin) equivalent to 50 mg/mL phenytoin sodium after administration. Cerebyx (fosphenytoin sodium injection) is supplied in vials as a ready-mixed solution in Water for Injection, USP, and Tromethamine, USP (TRIS), buffer adjusted to pH 8.6 to 9.0 with either Hydrochloric Acid, NF, or Sodium Hydroxide, NF. Cerebyx (fosphenytoin sodium injection) is a clear, colorless to pale yellow, sterile solution. The chemical name of fosphenytoin is 5,5-diphenyl-3-[[phosphonooxy)methyl]-2,4-imidazolidinedione disodium salt.
FIRST AID MEASURES

Eye contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

FIRE FIGHTING MEASURES
Flammability None anticipated for this aqueous product.
Fire & Explosion Hazard None anticipated for this aqueous product.
Extinguishing media As with any fire, use extinguishing media appropriate for primary cause of fire.
Special Fire Fighting Procedures
No special provisions required beyond normal firefighting equipment such as

**ACCIDENTAL RELEASE MEASURES**
Spill Cleanup and Disposal Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

**HANDLING AND STORAGE**
Handling No special handling required under conditions of normal product use.
Storage No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.
Special Precautions No special precautions required for hazard control.

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