Cerebyx®
(Fosphenytoin Sodium Injection)
500 mg PE/10 mL
(50 mg PE/mL)
(PE = phenytoin sodium equivalents)
For Intramuscular or Intravenous Use

Each vial contains fosphenytoin sodium 750 mg equivalent to 500 mg of phenytoin sodium. Fosphenytoin sodium solution is a sterile, isotonic, pH-adjusted, hydrochloric acid and citric acid buffered solution. Solutions are for single use only. Each milliliter contains 50 mg PE/mL and is buffered with hydrochloric acid and citric acid to adjust the pH to between 4.5 and 5.5.

DOSE AND USE: See package insert for full prescribing information.

Contraindications:
Cerebyx is contraindicated in patients who have demonstrated a hypersensitivity to any of its components or who have a history of seizures unresponsive to therapy with phenytoin.

Precautions:

1. Administer intramuscular injections deep into the muscle, avoiding superficial injections. Administer intravenous injections by direct injection into a vein. Administer in a hospital setting with medical personnel and equipment that can be used for emergency resuscitation. Do not save for use in the future. Do not use if color change occurs.

2. Monitor patients for signs and symptoms of phenytoin toxicity. The development of toxicity may require dosage adjustments and in severe cases, hospitalization. Discontinue therapy in life-threatening toxicity.

3. Dosages of phenytoin may be increased at intervals of 1 to 2 days until the desired clinical response is achieved. Dosages may be increased or decreased slowly to avoid toxicity or drug accumulation, respectively.

4. Cerebyx may cause a dose-related increase in serum transaminase levels. Obtain baseline and periodic liver function tests. If hepatic enzyme levels increase, discontinue therapy.

5. Cerebyx contains citric acid as a buffer. Citric acid is metabolized in the liver and may cause hyperchloremic acidosis in patients with renal impairment.

6. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected intramuscularly.

7. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected intravenously.

8. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected subcutaneously.

9. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected intracerebrally.

10. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected intraspinal.

11. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected retroperitoneal.

12. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected subconjunctival.

13. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected submucosal.

14. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected intratracheal.

15. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected subcutaneous.

16. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected intradermal.

17. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected intravascular.

18. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected intraventricular.

19. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected intrathecal.

20. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected intraperitoneal.

21. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected intrasynovial.

22. Cerebyx contains hydrochloric acid as a buffer. Hydrochloric acid is a corrosive acid that may cause tissue damage if injected intracostal.
### Table: Project Information

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<th>Project No.</th>
<th>Artwork Number</th>
<th>Description</th>
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### Additional Info:

- **Project Name:** Pfizer Injectables
- **Artwork Details:**
  - Sizes: 3" x 0.9449" (L x W)
  - Drawing No.: DWG-102365-00
  - SKU No.: F000015199
  - Item: Label

**Changes:**
- **Reviewer:** GA
- **Status:** OK
- **Approval:** OK

Reference ID: 3393659
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ERIC P BASTINGS
10/22/2013