FOLIC ACID- folic acid injection, solution
X-GEN Pharmaceuticals, Inc.

Folic Acid Injection, USP

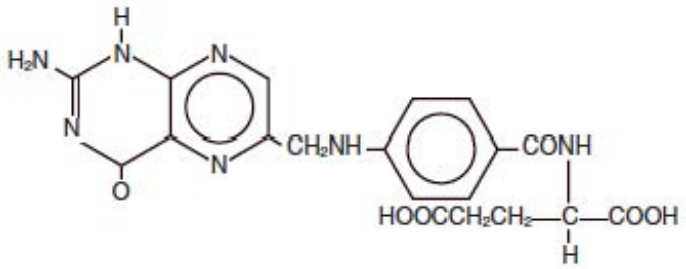
FOLIC ACID INJECTION, USP

Rx only

DESCRIPTION:

Folic Acid Injection, USP is a sterile, nonpyrogenic solution of sodium folate (prepared by the addition of sodium hydroxide to folic acid) in Water for Injection, USP intended for intramuscular (IM), intravenous (IV) or subcutaneous (SC) use.

Folic Acid is a complex organic compound present in liver, yeast and other substances, which may be prepared synthetically. It is a yellow or yellowish orange, odorless crystalline powder. It is very slightly soluble in water, insoluble in alcohol, chloroform, ether; readily dissolves in dilute solutions of alkali hydroxides and carbonates. It is chemically designated as: L-Glutamic acid, N-[4-[[(2-amino-1-4-dihydro-4-oxo-6-pteridinyl) methyl] amino]benzoyl]-, and has the following structural formula.



$C_{19}H_{19}N_7O_6$ M.W. 441.40

Each mL contains: Sodium folate (equivalent to 5 mg folic acid); edetate disodium 2 mg; benzyl alcohol 15 mg (added as preservative); Water for Injection, USP q.s. Hydrochloric acid and/or sodium hydroxide for pH adjustment (8.0 to 11.0).

CLINICAL PHARMACOLOGY:

In man, an exogenous source of folate is required for nucleoprotein synthesis and maintenance of normal erythropoiesis. Folic acid, whether given by mouth or parenterally, stimulates specifically the production of red blood cells, white blood cells and platelets in persons suffering from certain megaloblastic anemias.

INDICATIONS AND USAGE:

Folic Acid Injection, USP alone is effective in the treatment of megaloblastic anemias due to a deficiency of folic acid as may be seen in tropical or nontropical sprue, in anemias of nutritional origin, pregnancy, infancy or childhood.

WARNINGS:

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B_{12} is deficient.

This product contains benzyl alcohol. Benzyl alcohol has been reported to be associated with a fatal "Gasping Syndrome" in premature infants.

PRECAUTIONS:

Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive.

ADVERSE REACTIONS:

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

To report SUSPECTED ADVERSE REACTIONS, contact X-GEN Pharmaceuticals, Inc. at 1-866- 390-4411 or FDA at 1-800-FDA-1088 or www.fda. gov/medwatch.

DOSAGE AND ADMINISTRATION:

Parenteral Administration: Intramuscular (IM), intravenous (IV) and subcutaneous (SC) routes may be used if the disease is exceptionally severe or if gastrointestinal absorption may be, or is known to be, impaired.

Usual Therapeutic Dosage—In adults and children (regardless of age): up to 1 mg daily. Resistant cases may require larger doses.

Maintenance Level: When clinical symptoms have subsided and the blood picture has become normal, a maintenance level should be used, i.e., 0.1 mg for infants and up to 0.3 mg for children under four years of age, 0.4 mg for adults and children four or more years of age and 0.8 mg for pregnant and lactating women, per day, but never less than 0.1 mg per day. Patient should be kept under close supervision and adjustment of the maintenance level made if relapse appears imminent.

In the presence of alcoholism, hemolytic anemia, anticonvulsant therapy or chronic infection, the maintenance level may need to be increased.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED:

Folic Acid Injection, USP 50 mg per 10 mL (5 mg per mL) is available as:

Product NDC: 39822-1100-1

10 mL Multiple Dose, in a flip-top vial, packaged individually.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

PROTECT FROM LIGHT.

Retain vial in carton until contents are used.

Manufactured by:

Exela Pharma Sciences, LLC

Lenoir, NC 28645

Manufactured for:

X-GEN Pharmaceuticals, Inc.

Big Flats, NY 14814

Revised: August 2019

FOLI-PI-02

PACKAGE LABEL - PRINCIPAL DISPLAY - Folic Acid 10 mL Vial Label

NDC 39822-1100-1

Folic Acid Injection, USP

50 mg per 10 mL (5 mg per mL)

For intramuscular, intravenous or subcutaneous use.

10 mL Multiple Dose Vial

Rx only

FOLIC ACID

folic acid injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:39822-1100

Route of Administration	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE SODIUM (UNII: MP1J8420LU)	2 mg in 1 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	15 mg in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:39822-1100-1	1 in 1 CARTON	11/17/2019	
1		10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202522	11/17/2019	

Labeler - X-GEN Pharmaceuticals, Inc. (790169531)

Revised: 11/2019 X-GEN Pharmaceuticals, Inc.