

PYRIDOXINE HYDROCHLORIDE - pyridoxine hydrochloride injection, solution
Fresenius Kabi USA, LLC

Pyridoxine Hydrochloride Injection USP

100 mg/mL

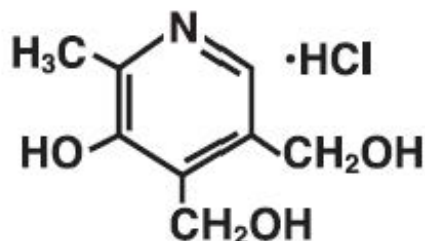
DESCRIPTION:

Pyridoxine Hydrochloride Injection, USP is a sterile solution of pyridoxine hydrochloride in Water for Injection. Each mL contains 100 mg pyridoxine hydrochloride and 0.5% chlorobutanol anhydrous (chloral deriv.). pH adjusted with sodium hydroxide if necessary (2.0 to 3.8).

Pyridoxine hydrochloride is a colorless or white crystal or a white crystalline powder. One gram dissolves in 5 mL of water. It is stable in air and is slowly affected by sunlight.

The chemical name is 2-methyl-3-hydroxy-4,5-bis (hydroxymethyl) pyridine hydrochloride.

The structural formula is:



CLINICAL PHARMACOLOGY:

Natural substances that have vitamin B₆ activity are pyridoxine in plants and pyridoxal or pyridoxamine in animals. All 3 are converted to pyridoxal phosphate by the enzyme pyridoxal kinase. The physiologically active forms of vitamin B₆ are pyridoxal phosphate (codecarboxylase) and pyridoxamine phosphate. Riboflavin is required for the conversion of pyridoxine phosphate to pyridoxal phosphate.

Vitamin B₆ acts as a coenzyme in the metabolism of protein, carbohydrate, and fat. In protein metabolism, it participates in the decarboxylation of amino acids, conversion of tryptophan to niacin or to serotonin (5-hydroxytryptamine), deamination, and transamination and transulfuration of amino acids. In carbohydrate metabolism, it is responsible for the breakdown of glycogen to glucose-1-phosphate.

The total adult body pool consists of 16 to 25 mg of pyridoxine. Its half-life appears to be 15 to 20 days. Vitamin B₆ is degraded to 4-pyridoxic acid in the liver. This metabolite is excreted in the urine.

The need for pyridoxine increases with the amount of protein in the diet. The tryptophan load test appears to uncover early vitamin B₆ deficiency by detecting xanthinuria. The average adult minimum daily requirement is about 1.25 mg. The "Recommended Dietary Allowance" of the National Academy of Sciences is estimated to be as much as 2.2 mg for adults and 2.5 mg for pregnant and lactating women. The requirements are more in persons having certain genetic defects or those being treated with isonicotinic acid hydrazide (INHJ) or oral contraceptives.

INDICATIONS AND USAGE:

Pyridoxine Hydrochloride Injection is effective for the treatment of pyridoxine deficiency as seen in

the following:

Inadequate dietary intake.

Drug-induced deficiency, as from isoniazid (INH) or oral contraceptives.

Inborn errors of metabolism, e.g., vitamin B₆ dependent convulsions or vitamin B₆ responsive anemia.

The parenteral route is indicated when oral administration is not feasible as in anorexia, nausea and vomiting, and preoperative and postoperative conditions. It is also indicated when gastrointestinal absorption is impaired.

CONTRAINDICATIONS:

A history of sensitivity to pyridoxine or to any of the ingredients in Pyridoxine Hydrochloride Injection, USP is a contraindication.

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.

PRECAUTIONS:

General

Single deficiency, as of pyridoxine alone, is rare. Multiple vitamin deficiency is to be expected in any inadequate diet. Patients treated with levodopa should avoid supplemental vitamins that contain more than 5 mg pyridoxine in the daily dose.

Women taking oral contraceptives may exhibit increased pyridoxine requirements.

Drug Interactions

Pyridoxine supplements should not be given to patients receiving levodopa, because the action of the latter drug is antagonized by pyridoxine. However, this vitamin may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa.

Pregnancy

Pregnancy Category A—The requirement for pyridoxine appears to be increased during pregnancy. Pyridoxine is sometimes of value in the treatment of nausea and vomiting of pregnancy.

Nursing Mothers

The need for pyridoxine is increased during lactation. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when pyridoxine hydrochloride is administered to a nursing woman.

Usage in Children

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS:

Paresthesia, somnolence, and low serum folic acid levels have been reported.

DRUG ABUSE AND DEPENDENCE:

Symptoms of dependence have been noted in adults given only 200 mg daily, followed by withdrawal.

OVERDOSAGE:

Pyridoxine given to animals in amounts of 3 to 4 g/kg of body weight produces convulsions and death. In man, a dose of 25 mg/kg of body weight is well tolerated.

DOSAGE AND ADMINISTRATION:

Pyridoxine Hydrochloride Injection may be administered intramuscularly or intravenously. In cases of dietary deficiency, the dosage is 10 to 20 mg daily for 3 weeks. Follow-up treatment is recommended daily for several weeks with an oral therapeutic multivitamin preparation containing 2 to 5 mg pyridoxine. Poor dietary habits should be corrected, and an adequate, well balanced diet should be prescribed.

The vitamin B₆ dependency syndrome may require a therapeutic dosage of as much as 600 mg a day and a daily intake of 30 mg for life.

In deficiencies due to INH, the dosage is 100 mg daily for 3 weeks followed by a 30 mg maintenance dose daily.

In poisoning caused by ingestion of more than 10 g of INH, an equal amount of pyridoxine should be given — 4 g intravenously followed by 1 g intramuscularly every 30 minutes.

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

HOW SUPPLIED:

Pyridoxine Hydrochloride Injection, USP is supplied as:

Product No.	NDC No.	Strength	
1801	63323-180-01	100 mg per mL	1 mL fill in a 2 mL multiple dose vial, in packages of 25.

PROTECT FROM LIGHT.

Use only if solution is clear and seal intact.

Sterile.

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



45817F

Revised: March 2015

PACKAGE LABEL - PRINCIPAL DISPLAY - Pyridoxine HCl 1 mL Multiple Dose Vial Label

NDC 63323-180-01

1801

PYRIDOXINE HCl INJECTION, USP

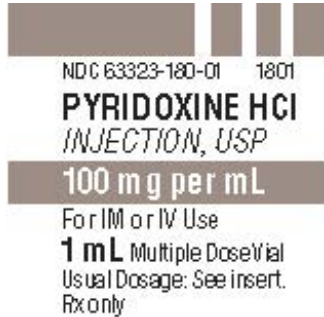
100 mg per mL

For IM or IV Use

1 mL Multiple Dose Vial

Usual Dosage: See insert.

Rx only



PACKAGE LABEL - PRINCIPAL DISPLAY - Pyridoxine HCl 1 mL Multiple Dose Vial Tray Label

NDC 63323-180-01

1801

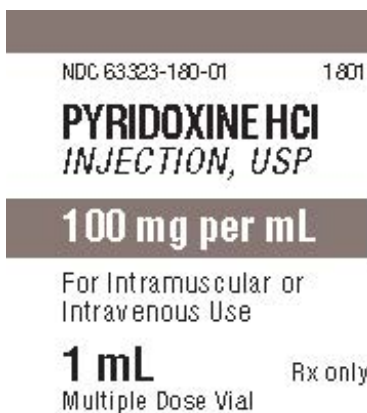
PYRIDOXINE HCl INJECTION, USP

100 mg per mL

For Intramuscular or
Intravenous Use

1 mL Rx only

Multiple Dose Vial



PYRIDOXINE HYDROCHLORIDE

pyridoxine hydrochloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63323-180
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRIDOXINE HYDROCHLORIDE (UNII: 68 Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CHLOROBUTANOL (UNII: HM4YQM8WRC)	5 mg in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63323-180-01	25 in 1 TRAY		
1		1 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA080618	08/14/1972	

Labeler - Fresenius Kabi USA, LLC (608775388)**Establishment**

Name	Address	ID/FEI	Business Operations
Fresenius Kabi USA, LLC		840771732	MANUFACTURE(63323-180)

Revised: 3/2015

Fresenius Kabi USA, LLC