

PYRIDOXINE HCl- pyridoxine hci injection, solution
HF Acquisition Co LLC, DBA HealthFirst

PYRIDOXINE HCl INJECTION, USP 100mg per mL 1mL VIAL

SPL UNCLASSIFIED

100 mg/mL

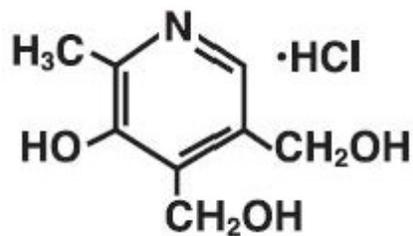
DESCRIPTION

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 xanthinurea. 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 (INH) or oral contraceptives.

INDICATIONS & 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

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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 & 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 HCl INJECTION, USP is supplied in the following dosage forms.

NDC 51662-1410-1

PYRIDOXINE HCl INJECTION, USP 100mg per mL 1mL VIAL

NDC 51662-1410-2

PYRIDOXINE HCl INJECTION, USP 100mg per mL 1mL VIAL, 1 VIAL PER POUCH

NDC 51662-1410-3

PYRIDOXINE HCl INJECTION, USP 100mg per mL 1mL VIAL, 1 VIAL PER POUCH, 25 POUCHES PER CASE

HF Acquisition Co LLC, DBA HealthFirst
Mukilteo, WA 98275

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].

SPL UNCLASSIFIED

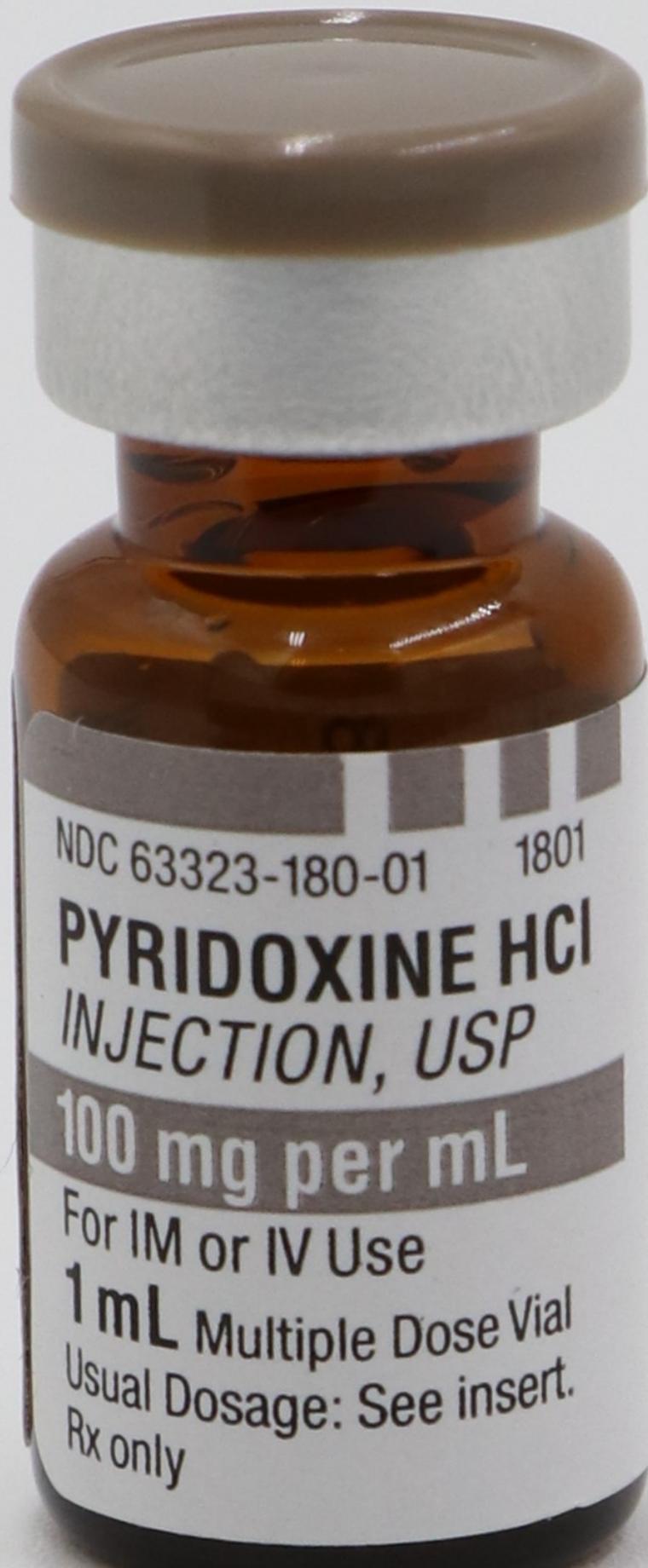
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Revised: March 2015



PRINCIPAL DISPLAY PANEL, VIAL LABEL





NDC 63323-180-01 1801

PYRIDOXINE HCl
INJECTION, USP

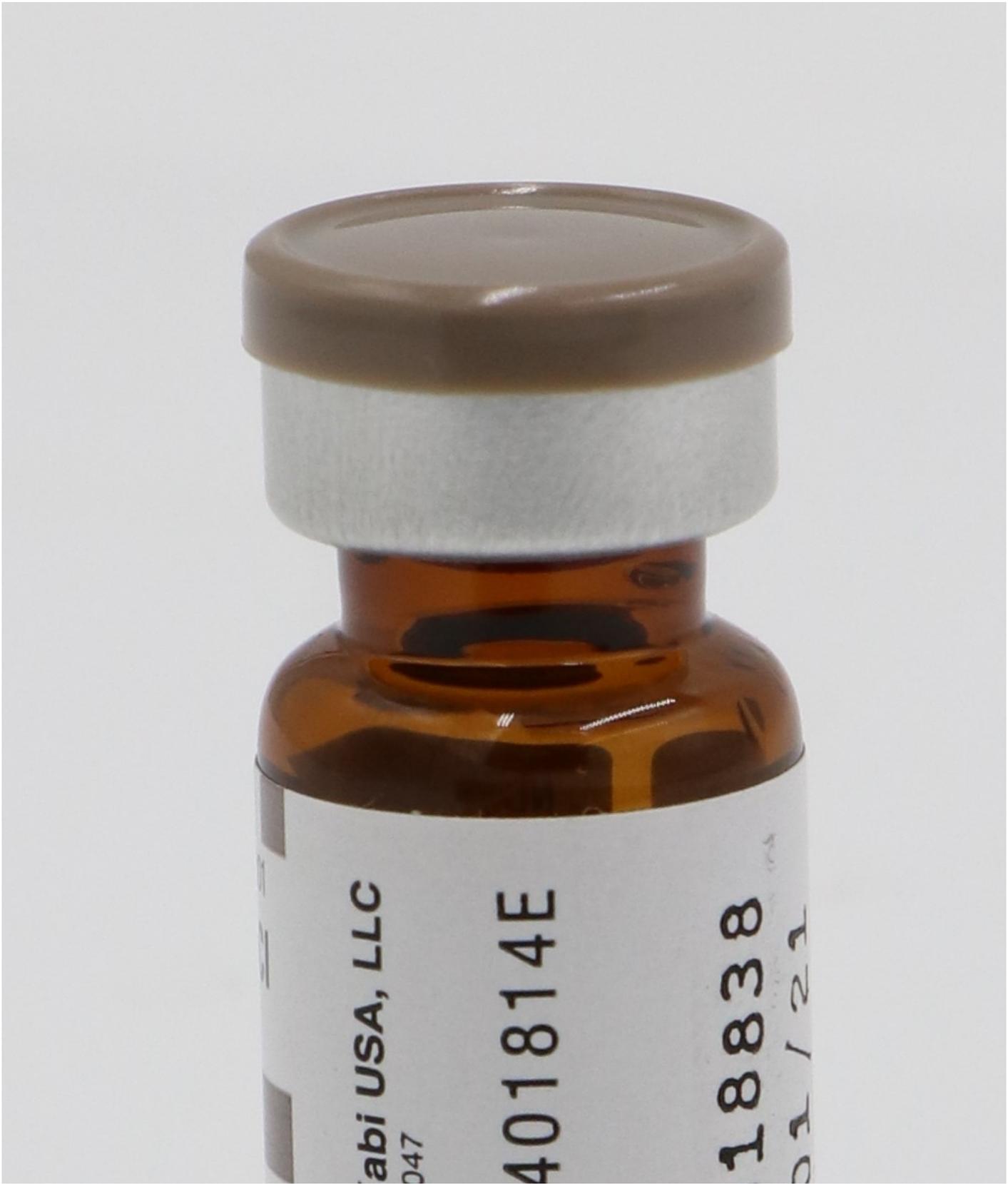
100 mg per mL

For IM or IV Use

1 mL Multiple Dose Vial

Usual Dosage: See insert.

Rx only



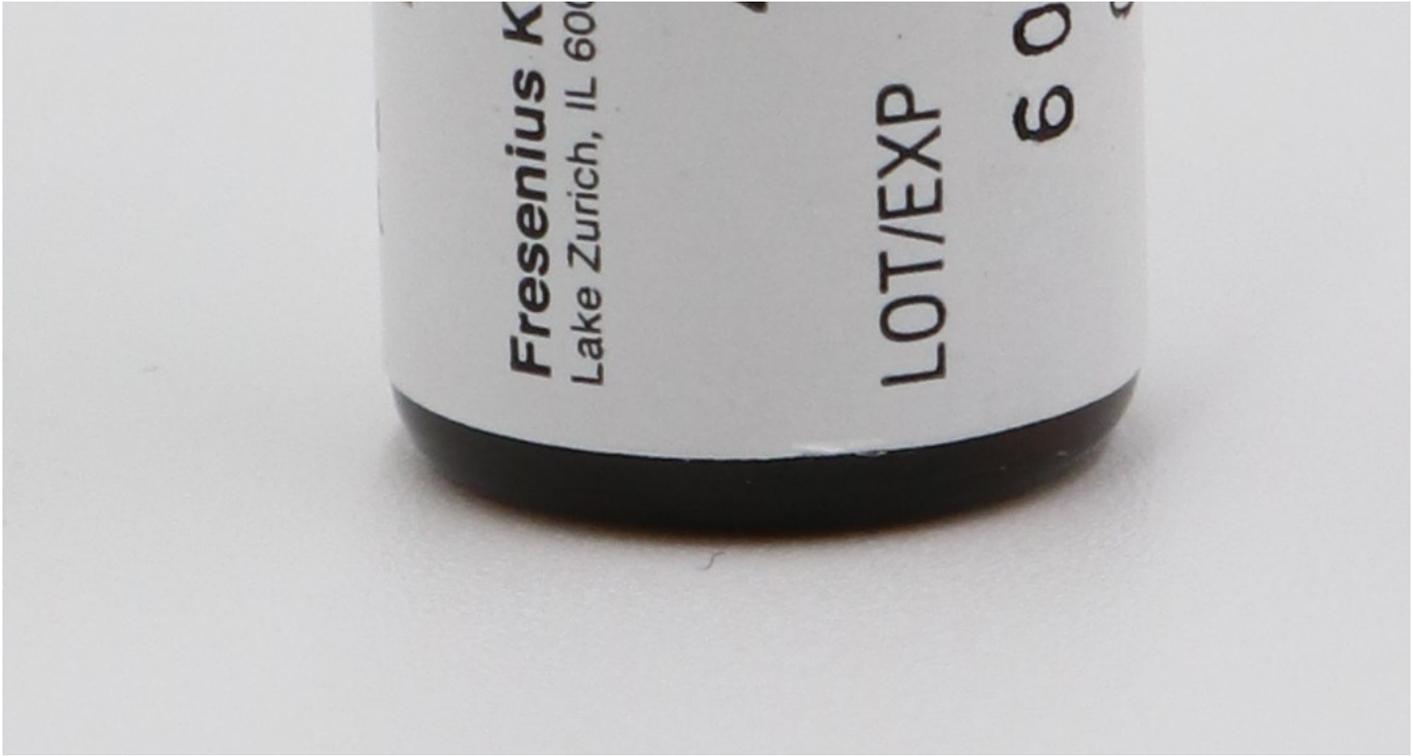
abi USA, LLC

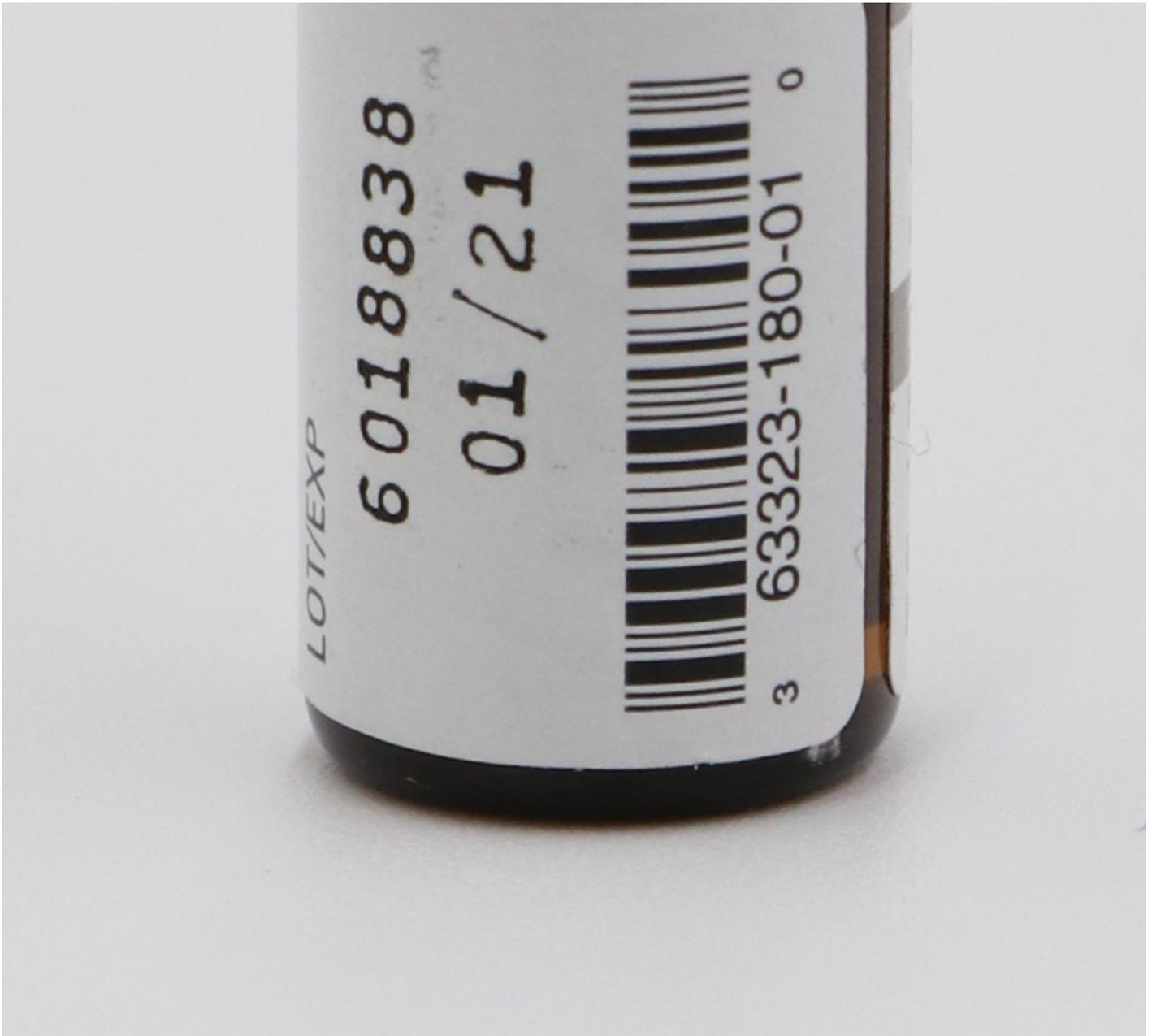
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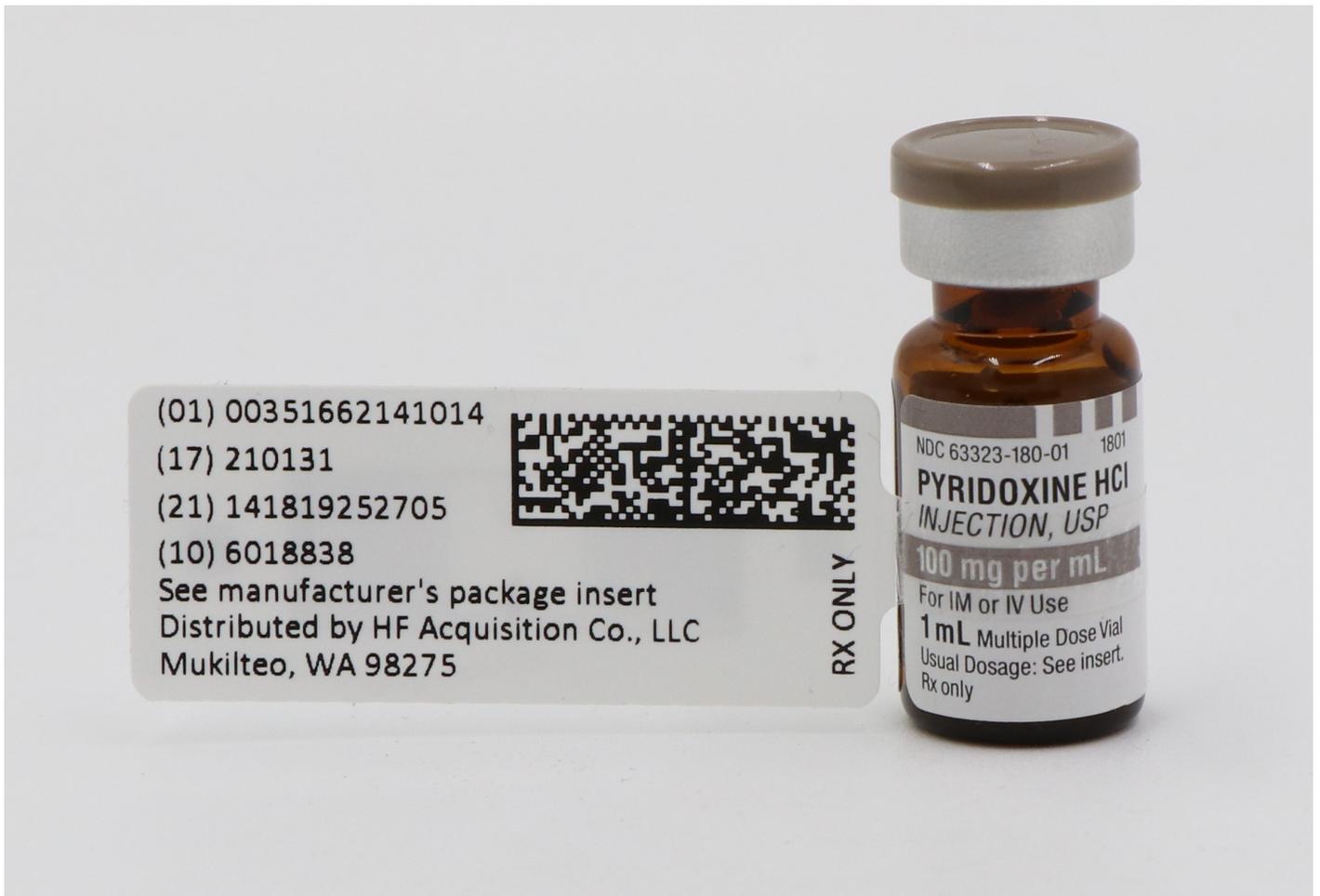
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PRINCIPAL DISPLAY PANEL, SERIALIZED LABELING



PRINCIPAL DISPLAY PANEL - NDC 51662-1410-2 POUCH LABELING

NDC 51662-1410-2 POUCH LABELING

PYRIDOXINE HCL INJECTION, USP 100mg PER
mL 1mL VIAL

NDC: 51662-1418-2
LOT: 123456
EXP: 2038-01-01

(01) 00351662141821
(10) 123456
(17) 300101
(21) 104780662878

FOR INTRAMUSCULAR OR INTRAVENOUS USE. STERILE. EACH mL
CONTAINS: PYRIDOXINE HCL 100mg; CHLOROBUTANOL ANHYDROUS
(CHLORAL DERIV.) 0.5%; WATER FOR INJECTION q. s. pH ADJUSTED
WITH SODIUM HYDROXIDE IF NECESSARY. CONTAINS NO MORE THAN 3,150
mcg/L OF ALUMINUM. USUAL DOSAGE: SEE INSERT. PROTECT FROM
LIGHT. USE ONLY IF SOLUTION IS CLEAR AND SEAL INTACT. STORE AT 20°
TO 25°C (68° TO 77°F) [SEE USP CONTROLLED ROOM TEMPERATURE].

See manufacturer's package insert
ORIGINAL MFG NDC: 63323-180-01

RX ONLY

Manufactured by HF Acquisition Co., LLC
Mukilteo, WA 98275



NDC 63323-180-00 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

Fresenius Kabi
Lake Zurich, IL 60047
www.fresenius-kabi.com/us

401814F

LOT/EXP



PRINCIPAL DISPLAY PANEL - NDC 51662-1410-3 CASE LABELING

NDC 51662-1410-3 CASE LABELING

PYRIDOXINE HCL INJECTION, USP 100mg PER
mL 1mL VIAL (CASE OF 25)

NDC: 51662-1410-3
LOT: 123456
EXP: 2030-01-01

(01) 40351662141036
(10) 123456
(17) 300101
(21) 242563785318

FOR INTRAMUSCULAR OR INTRAVENOUS USE, STERILE. EACH mL
CONTAINS: PYRIDOXINE HCL 100mg; CHLOROBUTANOL ANHYDROUS
(CHLORAL DERIV.) 0.5%; WATER FOR INJECTION q.s. pH ADJUSTED
WITH SODIUM HYDROXIDE IF NECESSARY. CONTAINS NO MORE THAN 3,150
mcg/L OF ALUMINUM. USUAL DOSAGE: SEE INSERT. PROTECT FROM
LIGHT. USE ONLY IF SOLUTION IS CLEAR AND SEAL INTACT. STORE AT 20°
TO 25°C (68° TO 77°F) [SEE USP CONTROLLED ROOM TEMPERATURE].

CASE

See manufacturer's package insert
ORIGINAL MFG NDC: 63323-180-01
RX ONLY
Manufactured by HF Acquisition Co., LLC
Mukilteo, WA 98275



NDC 51662-1410-3 SERIALIZED RFID LABELING

(01)40351662141036
(17)230919
(21)351662141212
(10)HF1234TESTING

SEE MANUFACTURE'S INSERT
DISTRIBUTED BY HF ACQUISITIONS CO., LLC
MUKILTEO, WA 98275

RX ONLY



PYRIDOXINE HCl

pyridoxine hci injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:51662-1410(NDC:63323- 180)
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	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:51662-1410-1	1 mL in 1 VIAL; Type 0: Not a Combination Product	10/08/2019	
2	NDC:51662-1410-3	25 in 1 CASE	12/11/2022	
2	NDC:51662-1410-2	1 in 1 POUCH		
2		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	10/08/2019	

Labeler - HF Acquisition Co LLC, DBA HealthFirst (045657305)

Registrant - HF Acquisition Co LLC, DBA HealthFirst (045657305)

Establishment

Name	Address	ID/FEI	Business Operations
HF Acquisition Co LLC, DBA HealthFirst		045657305	relabel(51662-1410)

Revised: 1/2024

HF Acquisition Co LLC, DBA HealthFirst