DEXTROSE- dextrose injection, solution
HF Acquisition Co LLC, DBA HealthFirst

5% DEXTROSE INJECTION

SPL UNCLASSIFIED

Dextrose Injection, USP
Flexible Plastic Container Rx only

DESCRIPTION

Dextrose Injection, USP solutions are sterile and nonpyrogenic. They are parenteral solutions containing various concentrations of dextrose in water for injection intended for intravenous administration.

Each 100 mL of 5% Dextrose Injection, USP, contains dextrose, hydrous 5 g in water for injection. The caloric value is 170 kcal/L. The osmolarity is 252 mOsmol/L (calc.), which is slightly hypotonic.

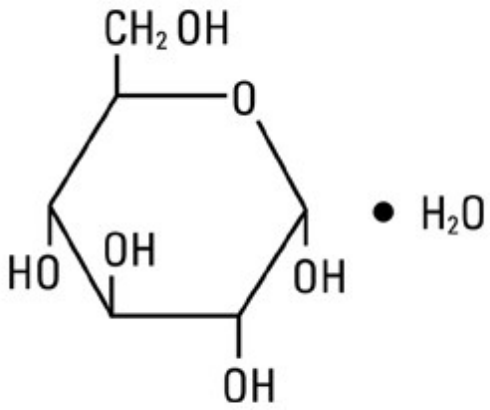
Each 100 mL of 10% Dextrose Injection, USP, contains dextrose, hydrous 10 g in water for injection. The caloric value is 340 kcal/L. The osmolarity is 505 mOsmol/L (calc.), which is hypertonic.

The pH for both concentrations is 4.3 (3.2 to 6.5).

The solutions contain no bacteriostat, antimicrobial agent or added buffer and each is intended only as a single-dose injection. When smaller doses are required the unused portion should be discarded.

The solutions are parenteral fluid and nutrient replenishers.

Dextrose, USP is chemically designated D-glucose monohydrate ($C_6H_{12}O_6 \cdot H_2O$), a hexose sugar freely soluble in water. It has the following structural formula:



Water for Injection, USP is chemically designated H2O.

The flexible plastic container is fabricated from a specially formulated polyvinylchloride. Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials. Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period.

CLINICAL PHARMACOLOGY

When administered intravenously, these solutions provide a source of water and carbohydrate.

Isotonic and hypertonic concentrations of dextrose are suitable for parenteral maintenance of water requirements when salt is not needed or should be avoided.

Solutions containing carbohydrate in the form of dextrose restore blood glucose levels and provide calories. Carbohydrate in the form of dextrose may aid in minimizing liver glycogen depletion and exerts a protein-sparing action. Dextrose injected parenterally undergoes oxidation to carbon dioxide and water.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirements range from two to three liters (1.0 to 1.5 liters each

for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na+) plays a major role in maintaining physiologic equilibrium.

NDICATIONS & USAGE

Intravenous solutions containing dextrose are indicated for parenteral replenishment of fluid and minimal carbohydrate calories as required by the clinical condition of the patient.

CONTRAINDICATIONS

Dextrose Injection without electrolytes should not be administered simultaneously with blood through the same infusion set because of the possibility that pseudoagglutination of red cells may occur.

WARNINGS

Excessive administration of potassium-free solutions may result in significant hypokalemia.

The intravenous administration of these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

The risk of dilutional states is inversely proportional to the electrolyte concentrations of administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

PRECAUTIONS

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Solutions containing dextrose should be used with caution in patients with known subclinical or overt diabetes mellitus.

Do not administer unless solution is clear and container is undamaged. Discard unused portion.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies with Dextrose Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Pregnancy: Teratogenic effects

Pregnancy Category C. Animal reproduction studies have not been conducted with dextrose. It is also not known whether dextrose can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose should be given to a pregnant woman only if clearly needed.

Nursing Mothers: Caution should be exercised when Dextrose Injection, USP is administered to a nursing mother.

Pediatric Use: The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolarity and possible intracerebral hemorrhage.

Geriatric Use: An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. (See WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.)

DOSAGE & ADMINISTRATION

he dose is dependent upon the age, weight and clinical condition of the patient.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Drug Interactions

Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

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

INSTRUCTIONS FOR USE

To Open:

Tear outer wrap at notch and remove solution container. If supplemental medication is desired, follow directions below before preparing for administration.

To Add Medication

1.
Prepare additive port.
2.
Using aseptic technique and an additive delivery needle of appropriate length, puncture resealable additive port at target area, inner diaphragm and inject. Withdraw needle after injecting medication.
3.
The additive port may be protected by covering with an additive cap.
4.
Mix container contents thoroughly.

Preparation for Administration

(Use aseptic technique)

1.

Close flow control clamp of administration set.
2.
Remove cover from outlet port at bottom of container.
3.
Insert piercing pin of administration set into port with a twisting motion until the set is firmly seated.
NOTE: When using a vented administration set, replace bacterial retentive air filter with piercing pin cover. Insert piercing pin with twisting motion until shoulder of air filter housing rests against the outlet port flange.
4.
Suspend container from hanger.
5.
Squeeze and release drip chamber to establish proper fluid level in chamber.
6.
Attach venipuncture device to set.
7.
Open clamp to expel air from set and venipuncture device. Close clamp.
8.
Perform venipuncture.
9.
Regulate rate of administration with flow control clamp.

WARNING: Do not use flexible container in series connections.

HOW SUPPLIED

5% DEXTROSE INJECTION is supplied in the following dosage forms.
NDC 51662-1214-1
5% DEXTROSE INJECTION, USP 250mL BAG

NDC 51662-1306-1

5% DEXTROSE INJECTION, USP 100mL BAG

HF Acquisition Co LLC, DBA HealthFirst
Mukilteo, WA 98275

Also supplied in the following manufactures dosage forms

Dextrose Injection, USP is supplied in single-dose flexible plastic containers in various sizes and concentrations as shown in the accompanying Table.

NDC No.	Product	Container size (mL)
0409-7922-61	5% Dextrose Injection, USP	150
0409-7922-53	5% Dextrose Injection, USP	250
0409-7922-02	5% Dextrose Injection, USP	250
0409-7922-03	5% Dextrose Injection, USP	500
0409-7922-55	5% Dextrose Injection, USP	500
0409-7922-09	5% Dextrose Injection, USP	1000
0409-7923-20	5% Dextrose Injection, USP	25
0409-7923-36	5% Dextrose Injection, USP	50
0409-7923-13	5% Dextrose Injection, USP	50
0409-7923-23	5% Dextrose Injection, USP	100
0409-7923-37	5% Dextrose Injection, USP	100
0409-7930-02	10% Dextrose Injection, USP	250
0409-7930-03	10% Dextrose Injection, USP	500
0409-7930-09	10% Dextrose Injection, USP	1000

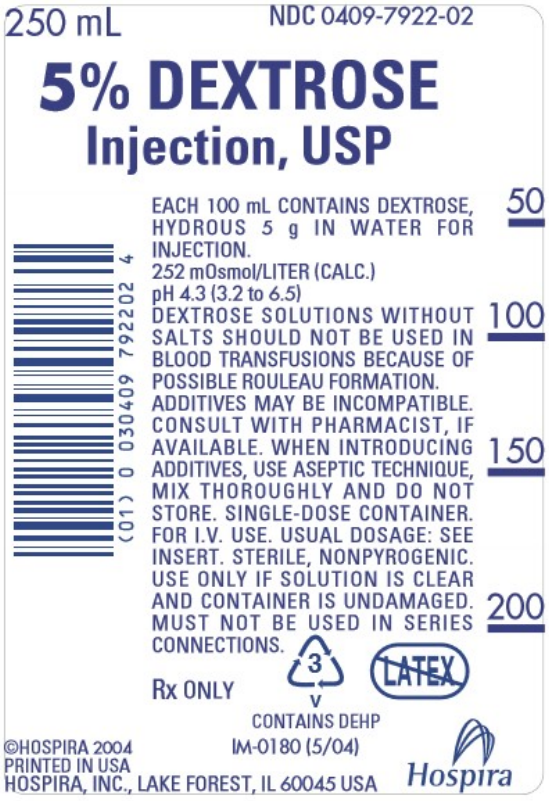
Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing.

Revised: June, 2010

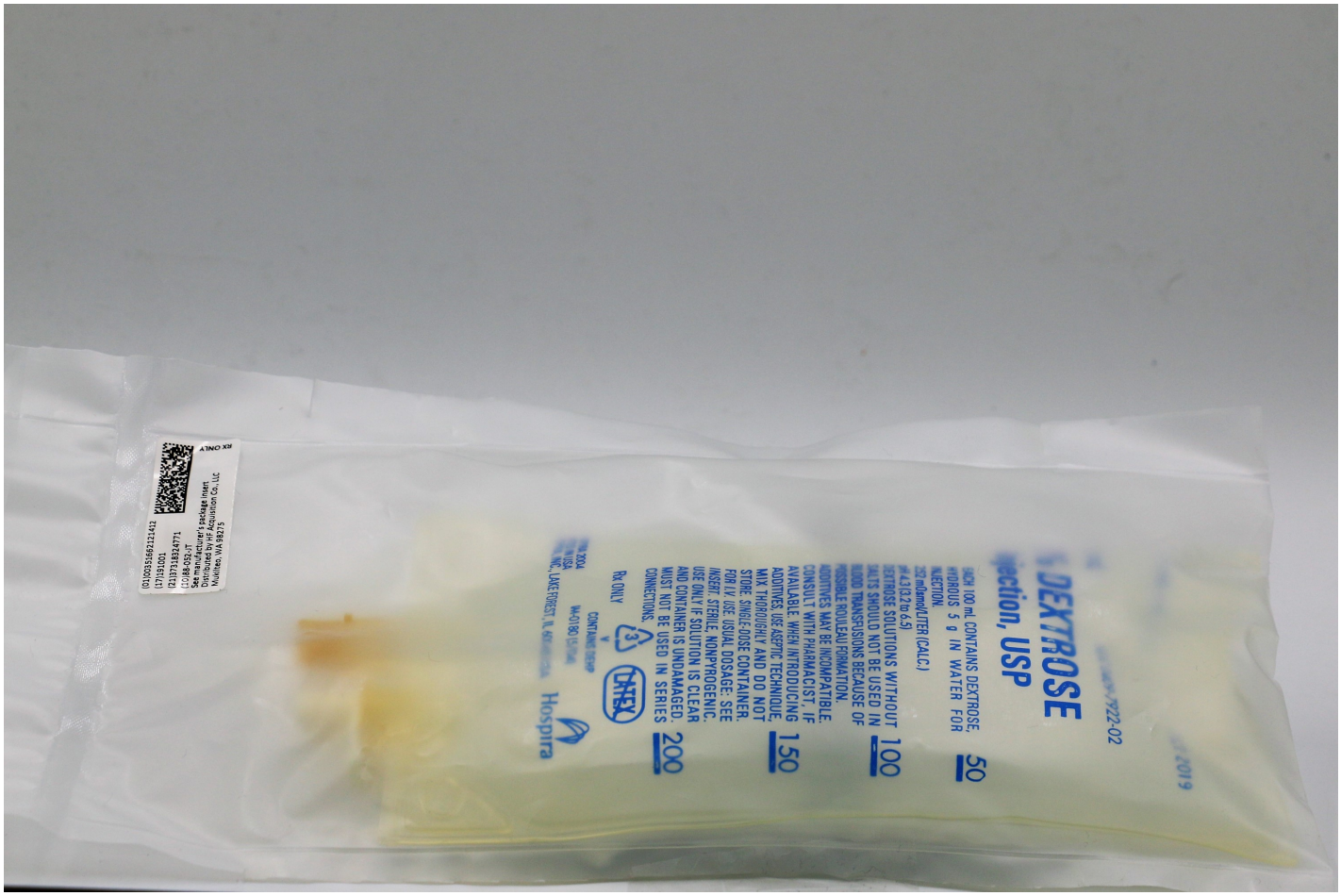
Printed in USA EN-2531

Hospira, Inc., Lake Forest, IL 60045 USA

PRINCIPAL DISPLAY PANEL, 250 mL BAG



PRINCIPAL DISPLAY PANEL, 250mL SERIALIZED



PRINCIPAL DISPLAY PANEL, 100mL BAG

PRINCIPAL DISPLAY PANEL, 100 mL SERIALIZED

100mL Serialized Bag

DEXTROSE

dextrose injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51662-1214(NDC:0409-7922)
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	5 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:51662-1214-1	1 in 1 POUCH	10/06/2018	
1		250 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA016367	10/06/2018	

DEXTROSE

dextrose injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51662-1306(NDC:0409-7923)
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51662-1306-1	1 in 1 POUCH	10/06/2018	
1		100 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA016367	10/06/2018	

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(51662-1214, 51662-1306)