DEXTROSE- dextrose monohydrate injection, solution
Hospira, Inc.

50% Dextrose Injection, USP
Concentrated Dextrose for
Intravenous Administration

NOTE: This solution is hypertonic - See WARNINGS and PRECAUTIONS.

LifeShield® Abboject® Syringe

Abboject® Syringe

Fliptop Container

Ansyr® II Plastic Syringe
Rx only

DESCRIPTION

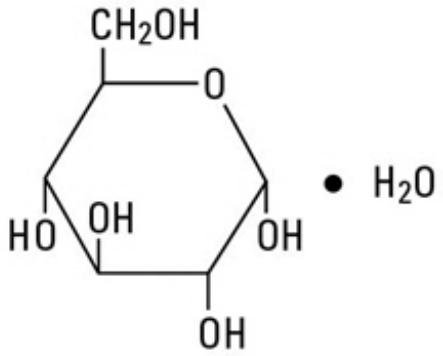
50% Dextrose Injection, USP is a sterile, nonpyrogenic, hypertonic solution of dextrose in water for injection for intravenous injection as a fluid and nutrient replenisher.

Each mL of fluid contains 0.5 g dextrose, hydrous which delivers 3.4 kcal/gram. The solution has an osmolarity of 2.53 mOsmol/mL (calc.), pH 3.2 to 6.5 and may contain sodium hydroxide and/or hydrochloric acid for pH adjustment.

The solution contains no bacteriostat, antimicrobial agent or added buffer (except for pH adjustment) and is intended only for use as a single-dose injection. When smaller doses are required, the unused portion should be discarded with the entire unit.

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

Dextrose, hydrous has the following structural formula:



Water for Injection, USP is chemically designated H_2O.

The syringe is molded from a specially formulated polypropylene. Water permeates from inside the container at an extremely slow rate which will have an insignificant effect on

solution concentration over the expected shelf life. 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 syringe material.

CLINICAL PHARMACOLOGY

When administered intravenously this solution restores blood glucose levels in hypoglycemia and provides a source of carbohydrate calories.

Carbohydrate in the form of dextrose may aid in minimizing liver glycogen depletion and exerts a protein-sparing action. Dextrose injection 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 requirement ranges 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.

INDICATIONS AND USAGE

50% Dextrose Injection is indicated in the treatment of insulin hypoglycemia (hyperinsulinemia or insulin shock) to restore blood glucose levels.

The solution is also indicated, after dilution, for intravenous infusion as a source of carbohydrate calories in patients whose oral intake is restricted or inadequate to maintain nutritional requirements. Slow infusion of hypertonic solutions is essential to ensure proper utilization of dextrose and avoid production of hyperglycemia.

CONTRAINDICATIONS

A concentrated dextrose solution should not be used when intracranial or intraspinal hemorrhage is present, nor in the presence of delirium tremens if the patient is already dehydrated.

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

50% Dextrose Injection is hypertonic and may cause phlebitis and thrombosis at the site of injection.

Significant hyperglycemia and possible hyperosmolar syndrome may result from too rapid administration. The physician should be aware of the symptoms of hyperosmolar syndrome, such as mental confusion and loss of consciousness, especially in patients

with chronic uremia and those with known carbohydrate intolerance.

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

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

For peripheral vein administration:

The solution should be given slowly, preferably through a small-bore needle into a large vein, to minimize venous irritation.

For central venous administration:

Concentrated dextrose should be administered via central vein only after suitable dilution.

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

Do not use unless the solution is clear and seal is intact. Discard unused portion.

Electrolyte deficits, particularly in serum potassium and phosphate, may occur during prolonged use of concentrated dextrose solutions. Blood electrolyte monitoring is essential and fluid and electrolyte imbalances should be corrected. Essential vitamins and minerals also should be provided as needed.

To minimize hyperglycemia and consequent glycosuria, it is desirable to monitor blood and urine glucose and if necessary, add insulin.

When a concentrated dextrose infusion is abruptly withdrawn, it is advisable to follow with the administration of 5% or 10% dextrose injection to avoid rebound hypoglycemia.

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

Care should be exercised to ensure that the needle is well within the lumen of the vein and that extravasation does not occur. If thrombosis should occur during administration, the injection should be stopped and corrective measures instituted.

Concentrated dextrose solutions should not be administered subcutaneously or intramuscularly.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Studies with solutions in polypropylene syringes have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Pregnancy:

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

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 50% Dextrose Injection, USP is administered to a nursing mother.

ADVERSE REACTIONS

Hyperosmolar syndrome, resulting from excessively rapid administration of concentrated dextrose may cause mental confusion and/or loss of consciousness.

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 during therapy, re-evaluate the patient and institute appropriate corrective measures. See **WARNINGS** and **PRECAUTIONS**.

DOSAGE AND ADMINISTRATION

For peripheral vein administration:

Injection of the solution should be made *slowly*.

The maximum rate at which dextrose can be infused without producing glycosuria is 0.5 g/kg of body weight/hour. About 95% of the dextrose is retained when infused at a rate of 0.8 g/kg/hr.

In insulin-induced hypoglycemia, intravenous injection of 10 to 25 grams of dextrose (20 to 50 mL of 50% dextrose) is usually adequate. Repeated doses and supportive treatment may be required in severe cases. A specimen for blood glucose determination should be taken before injecting the dextrose. In such emergencies, dextrose should be administered promptly without awaiting pretreatment test results.

For central venous administration:

For total parenteral nutrition 50% Dextrose Injection, USP is administered by slow intravenous infusion (a) after admixture with amino acid solutions via an indwelling catheter with the tip positioned in a large central vein, preferably the superior vena cava, or (b) after dilution with sterile water for injection. Dosage should be adjusted to meet individual patient requirements.

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.

The maximum rate of dextrose administration which does not result in glycosuria is the same as cited above.

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

HOW SUPPLIED

50% Dextrose Injection, USP is supplied in single-dose containers as follows:

Unit of Sale and Product Description	**Strength (Concentration)**	**NDC**
Bundle of 10 50 mL LifeShield® Abboject® Unit of Use Syringe with Male Luer Lock adapter and protected needle	25 g/50 mL (0.5 g/mL)	0409-4902-34
Bundle of 10 50 mL Single-Dose Abboject® Syringe with Male Luer Lock Adapter	25 g/50 mL (0.5 g/mL)	0409-0505-25
Tray of 25 50 mL Single-Dose Fliptop Vials	25 g/50 mL (0.5 g/mL)	0409-6648-02
Bundle of 10 50 mL Ansyr® II Plastic Syringe with syringe and barrel detached	25 g/50 mL (0.5 g/mL)	0409-7517-16

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

Abboject® is a trademark of Abbott Laboratories.

LifeShield® is the trademark of ICU Medical, Inc. and is used under license.

For Medical Information about 50% Dextrose Injection, please visit www.pfizermedinfo.com or call 1-800-438-1985.

Distributed by Hospira, Inc., Lake Forest, IL 60045 USA

LAB-1027-6.0

Revised: September 2023

PRINCIPAL DISPLAY PANEL - 50 mL Syringe Label - 0409-7517-66

50% DEXTROSE

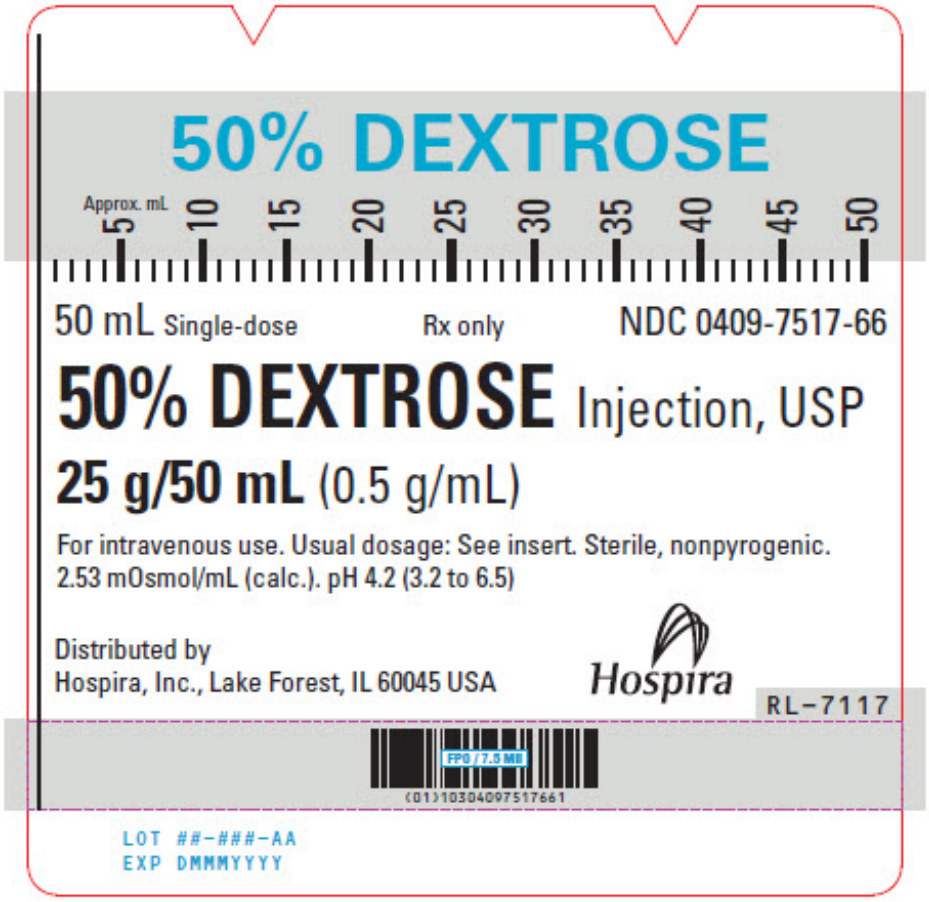
50 mL Single-dose
Rx only
NDC 0409-7517-66

50% DEXTROSE Injection, USP
25 g/50 mL (0.5 g/mL)

For intravenous use. Usual dosage: See insert. Sterile, nonpyrogenic.
2.53 mOsmol/mL (calc.). pH 4.2 (3.2 to 6.5)

Distributed by
Hospira, Inc., Lake Forest, IL 60045 USA
Hospira
RL-7117

LOT ##-###-AA
EXP DMMMYYYY



PRINCIPAL DISPLAY PANEL - 50 mL Syringe Carton - 0409-7517-66

50 mL
NDC 0409-7517-66

50%
DEXTROSE
Injection, USP

25 g/50 mL (0.5 g/mL)

Ansyr®II

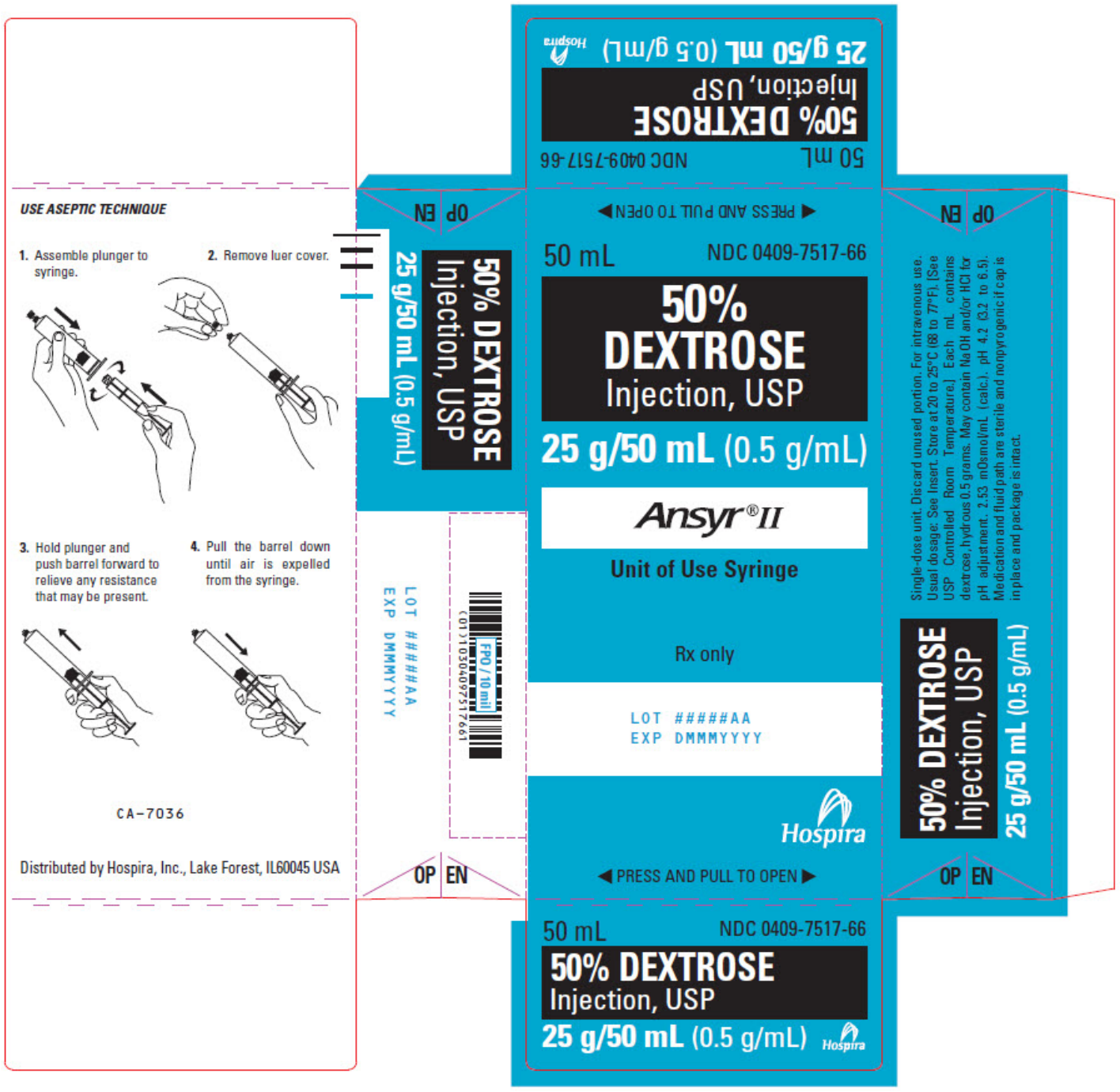
Unit of Use Syringe

Rx only

LOT #####AA
EXP DMMMYYYY

Hospira

◀ PRESS AND PULL TO OPEN ▶



PRINCIPAL DISPLAY PANEL - 50 mL Syringe Label - 0409-4902-64

50% DEXTROSE

50 mL Single-dose
Rx only
NDC 0409-4902-64

50% DEXTROSE Inj., USP
25 g/50 mL (0.5 g/mL)

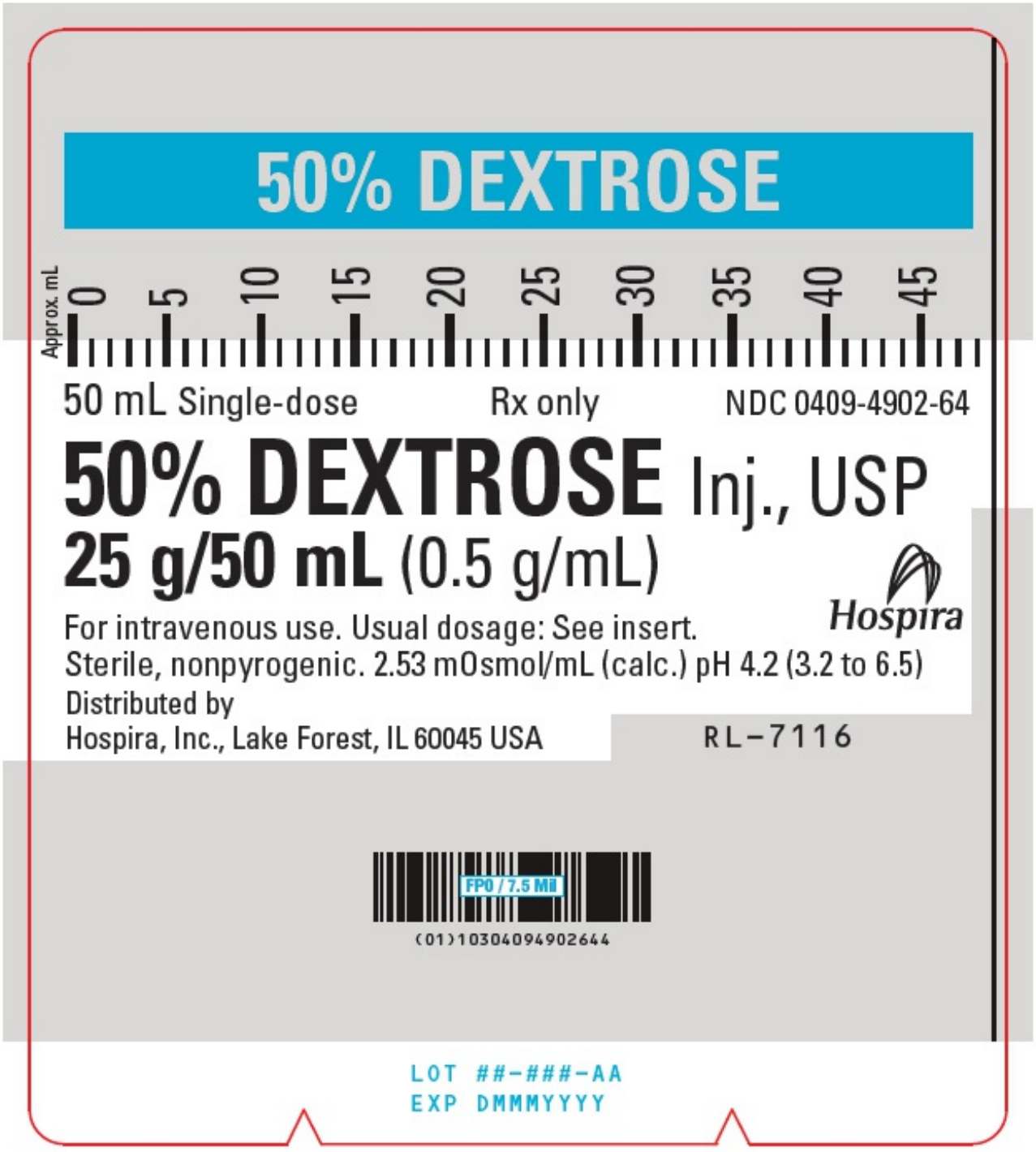
For intravenous use. Usual dosage: See insert.
Sterile, nonpyrogenic. 2.53 mOsmol/mL (calc.) pH 4.2 (3.2 to 6.5)
Distributed by
Hospira, Inc., Lake Forest, IL 60045 USA

Hospira

RL–7116

LOT ##–###–AA

EXP DMMMYYYY



PRINCIPAL DISPLAY PANEL - 50 mL Syringe Carton - 0409-4902-64

50 mL

NDC 0409-4902-64

50%
DEXTROSE
Injection, USP

25 g/50 mL
(0.5 g/mL)

LIFESHIELD®

Glass
ABBOJECT®
Unit of Use Syringe

with male luer lock
adapter and
18-Gauge protected needle

Rx only

Hospira

LOT #####AA

EXP DMMMYYYY

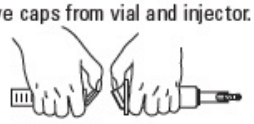
◀ PRESS AND PULL TO OPEN

CAUTION: Liquid in glass. Handle with care. Inspect vial for damage prior to assembly.

USE ASEPTIC TECHNIQUE

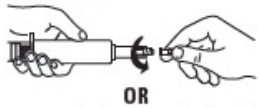
Do not assemble until ready to use.

1. Remove caps from vial and injector.



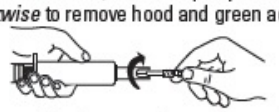
2. Insert vial into injector **without exerting excessive force.** Ensure that vial and injector are properly aligned. **Gently** rotate vial clockwise (about 3 turns) until medication enters needle. **If resistance is encountered, remove vial and repeat procedure.**

3. To access green male **luer lock adapter,** push yellow hood in and then twist counterclockwise.



OR

To access **needle,** twist and pull yellow hood *clockwise* to remove hood and green adapter.



4. Apply gentle downward pressure on vial to initiate liquid flow.

DO NOT APPLY EXCESSIVE FORCE TO VIAL.

Distributed by
Hospira, Inc., Lake Forest, IL 60045 USA

CA-7034

50% DEXTROSE
Injection, USP
25 g/50 mL (0.5 g/mL)

Each mL contains dextrose, hydrous 0.5 grams. May contain sodium hydroxide and/or hydrochloric acid for pH adjustment
253 mOsmol/mL (calc.)
Medication, fluid path and needle are sterile and nonpyrogenic if caps and needle cover are undisturbed and package is intact.

pH 4.2 (3.2 to 6.5).

OP EN

50 mL NDC 0409-4902-64

50% DEXTROSE
Injection, USP
25 g/50 mL (0.5 g/mL)

50 mL NDC 0409-4902-64

50% DEXTROSE
Injection, USP
25 g/50 mL
(0.5 g/mL)

LIFESHIELD®

Glass
ABBOJECT®
Unit of Use Syringe

with male luer lock adapter and 18-Gauge protected needle

Rx only

Hospira

LOT #####AA
EXP DMMMYYYY

◀ PRESS AND PULL TO OPEN

Single dose unit. Discard unused portion.
For intravenous use. Usual dose: See insert. To prevent needle-stick injuries, needles should not be recapped, purposely bent or broken by hand.
Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

Hospira

FPO / 10 mil

(01)10304094902644

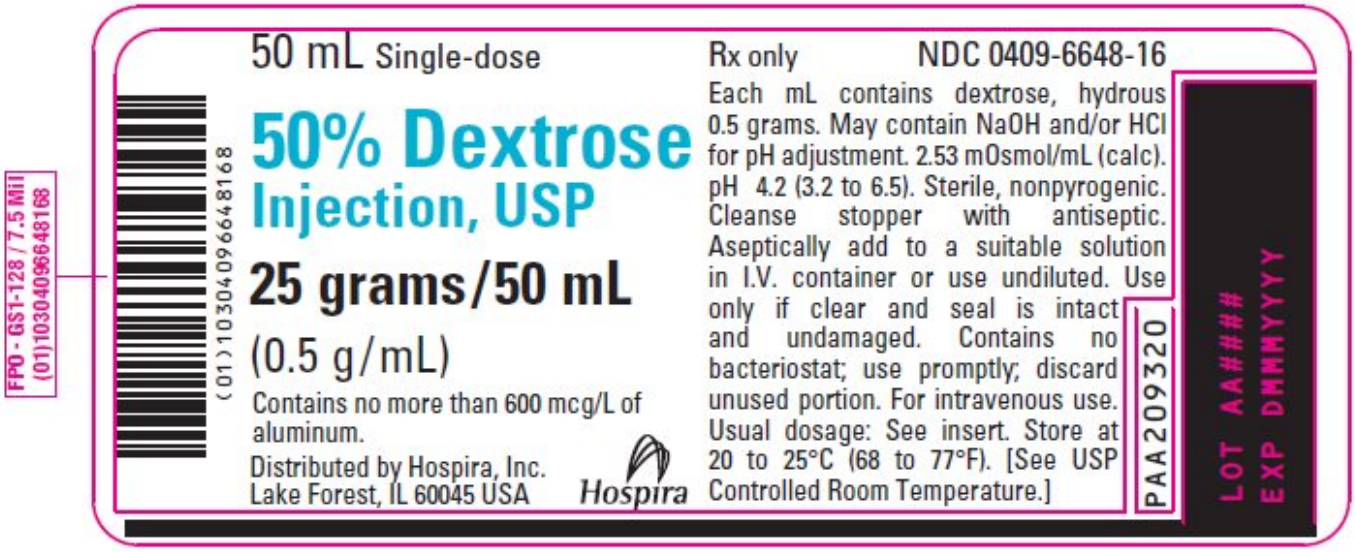
PRINCIPAL DISPLAY PANEL - 50 mL Vial Label - 0409-6648-16

50 mL Single-dose

50% Dextrose
Injection, USP

25 grams/50 mL
(0.5 g/mL)
Contains no more than 600 mcg/L of aluminum.
Distributed by Hospira, Inc.
Lake Forest, IL 60045 USA

Hospira



PRINCIPAL DISPLAY PANEL - 50 mL Vial Tray - 0409-6648-02

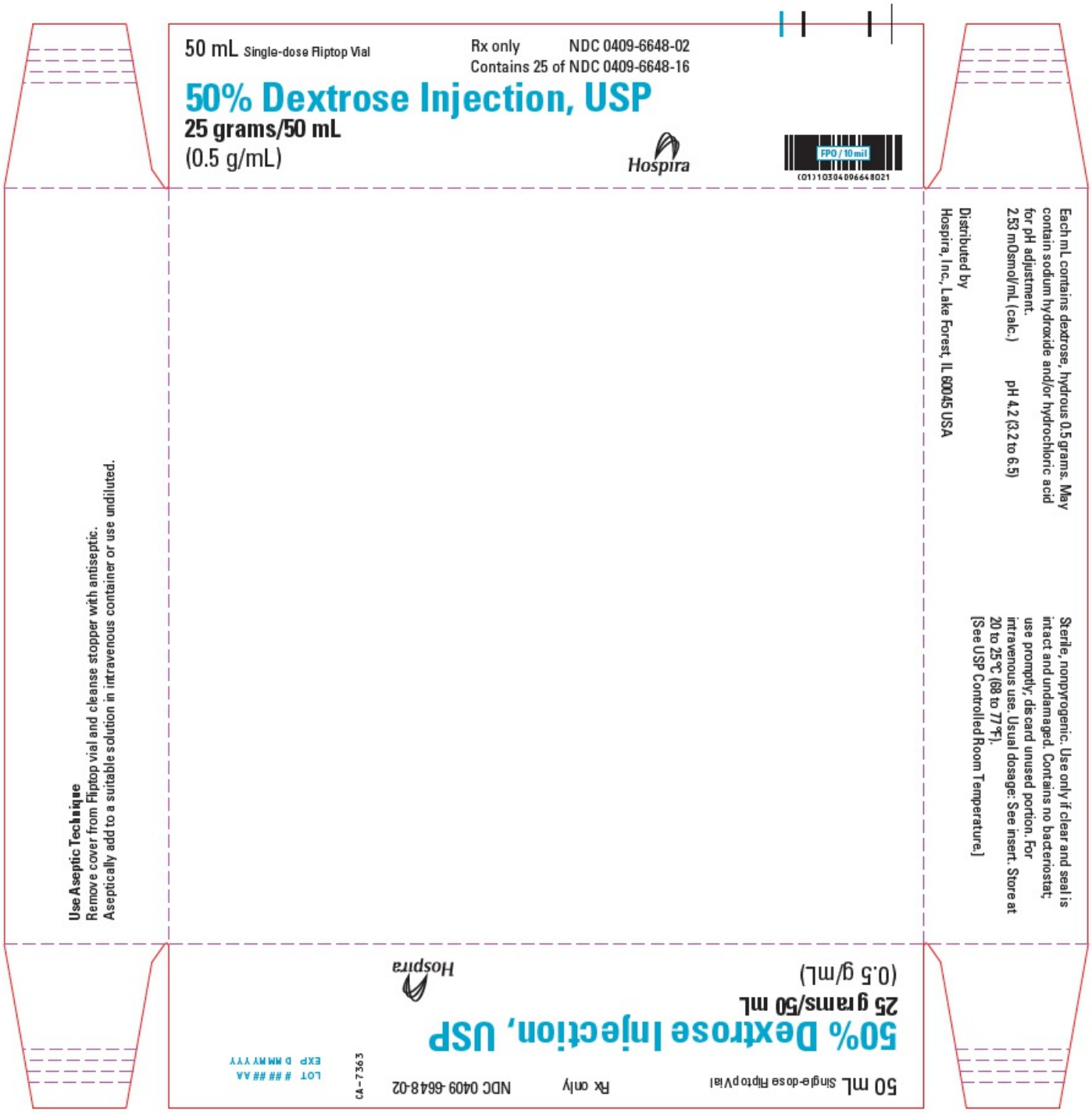
50 mL Single-dose Fliptop Vial

Rx only
NDC 0409-6648-02
Contains 25 of NDC 0409-6648-16

50% Dextrose Injection, USP

25 grams/50 mL
(0.5 g/mL)

Hospira



PRINCIPAL DISPLAY PANEL - 50 mL Syringe Label - 0409-0505-15

50 mL Single-Dose Syringe

Rx only

NDC 0409-0505-15

50% DEXTROSE Inj., USP
25 g/50 mL (0.5 g/mL)

For intravenous use. Recommended Dosage: See Prescribing Information.
Sterile, nonpyrogenic. 2.53 mOsmol/mL (calc.) pH 3.2 to 6.5

Distributed by Hospira, Inc.,
Lake Forest, IL 60045 USA

Hospira

PRINCIPAL DISPLAY PANEL - 50 mL Vial Carton - 0409-0505-15

PRESS AND PULL TO OPEN

50 mL

NDC 0409-0505-15

Rx only

50%
DEXTROSE
Injection, USP

25 g/50 mL
(0.5 g/mL)

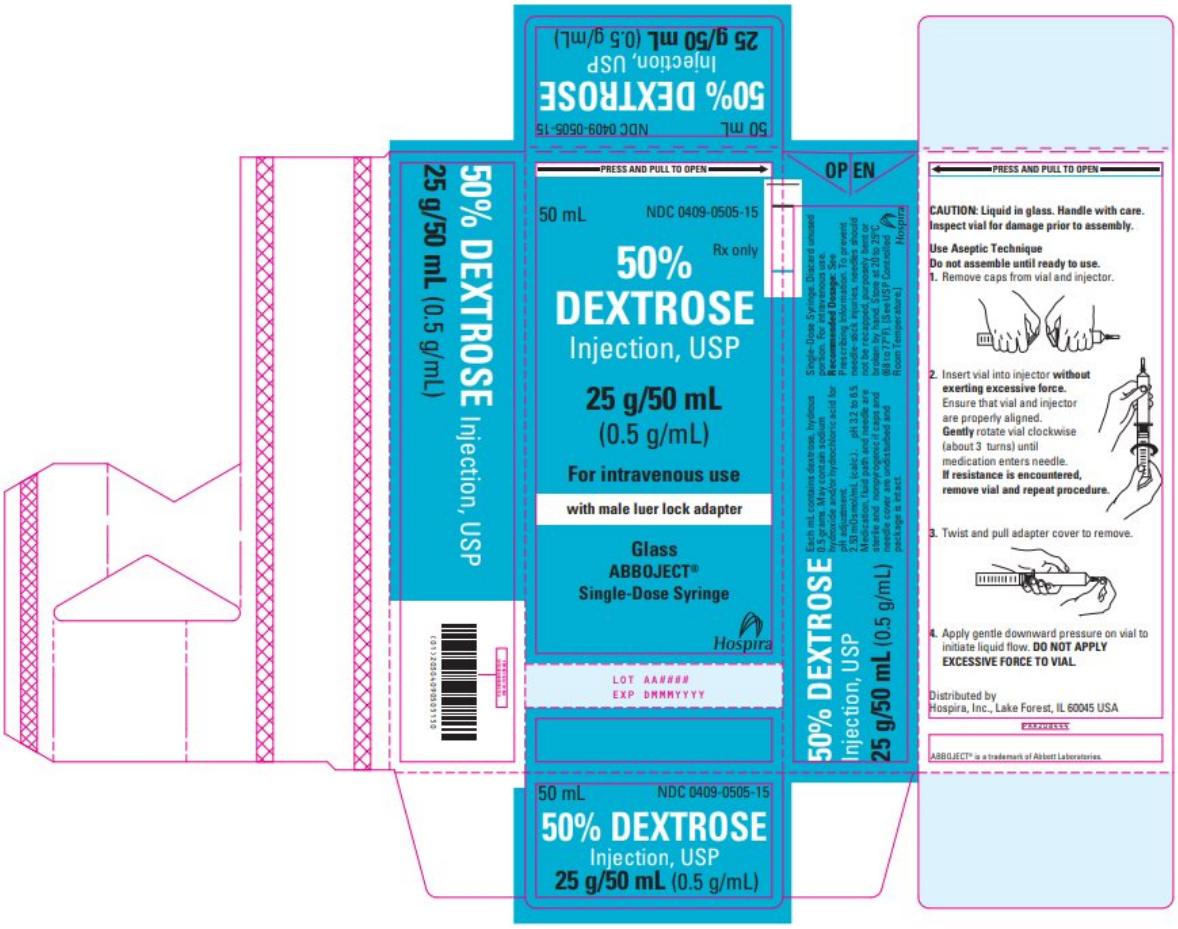
For intravenous use

with male luer lock adapter

Glass
Abboject®

Single-Dose Syringe

Hospira



DEXTROSE

dextrose monohydrate injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-7517
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	25 g in 50 mL

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

SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-7517-16	10 in 1 CONTAINER	12/02/2005	
1		1 in 1 CARTON		
1	NDC:0409-7517-66	50 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019445	12/02/2005	

DEXTROSE

dextrose monohydrate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-4902
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	25 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-4902-34	10 in 1 CONTAINER	12/07/2005	
1		1 in 1 CARTON		
1	NDC:0409-	50 mL in 1 SYRINGE; Type 1: Convenience Kit of		

1	4902-64	Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019445	12/07/2005	

DEXTROSE

dextrose monohydrate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-6648
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	25 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-6648-02	25 in 1 TRAY	03/31/2005	
1	NDC:0409-6648-16	50 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019445	03/31/2005	

DEXTROSE

dextrose monohydrate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-0505
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	25 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-0505-25	10 in 1 CONTAINER	04/15/2024	04/15/2024
1		1 in 1 CARTON		
1	NDC:0409-0505-15	50 mL in 1 SYRINGE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019445	04/15/2024	04/15/2024

Labeler - Hospira, Inc. (141588017)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		093132819	ANALYSIS(0409-7517, 0409-4902, 0409-6648, 0409-0505) , MANUFACTURE(0409-7517, 0409-4902, 0409-6648, 0409-0505) , PACK(0409-7517, 0409-4902, 0409-6648, 0409-0505) , LABEL(0409-7517, 0409-4902, 0409-6648, 0409-0505)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		827731089	ANALYSIS(0409-7517, 0409-4902, 0409-6648, 0409-0505)