DEXTROSE- dextrose monohydrate injection, solution
Fresenius Kabi USA, LLC

5% Dextrose Injection, USP

freeflex®

Rx only

DESCRIPTION:

5% Dextrose Injection, USP solution is sterile and nonpyrogenic. It is a parenteral solution containing dextrose in water for injection intended for intravenous administration.

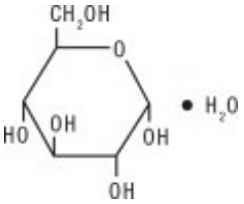
Each 100 mL of 5% Dextrose Injection, USP, contains dextrose monohydrate, 5 g in water for injection. The caloric value is 170 kcal/L. The osmolarity is 252 mOsmol/L (calc.), which is slightly hypotonic.

The solution pH is 4.3 (3.2 to 6.5).

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

5% Dextrose Injection, USP is a parenteral fluid and nutrient replenisher.

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 H_2O.

The flexible container is fabricated from a specially formulated non-plasticized film containing polypropylene and thermoplastic elastomers (**free***flex*® bag). The **free***flex*® + bag has a needle-free injection port and can accept standard luer lock syringes to add medication. The amount of water that can permeate from the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the flexible container can leach out certain of the container's chemical components in very small amounts within the expiration period. The suitability of the container material has been confirmed by tests in animals according to USP biological tests for plastic containers.

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 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:

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:

5% Dextrose Injection, USP 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 5% 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 5% 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 AND ADMINISTRATION:

The 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:

Check flexible container solution composition, lot number, and expiry date.

Do not remove solution container from its overwrap until immediately before use.

Use sterile equipment and aseptic technique.

To Open

1. Turn solution container over so that the text is face down. Using the pre-cut corner tabs, peel open the overwrap and remove solution container.
2. Check the solution container for leaks by squeezing firmly. If leaks are found, or if the seal is not intact, discard the solution.
3. Do not use if the solution is cloudy or a precipitate is present.

To Add Medication

The Additive port of the **free***flex*® + container accepts standard luer lock syringes. **Do not use a needle for additions.**

1. Identify LIGHT BLUE Additive Port with arrow pointing toward solution container.
2. Immediately before injecting additives, break off LIGHT BLUE Additive Port Cap with the arrow pointing toward solution container.
3. Hold base of LIGHT BLUE Additive Port.
4. Attach Luer Lock syringe to the threaded LIGHT BLUE Additive Port. Inject additive.
5. Mix solution container contents thoroughly.

Preparation for Administration

1. Immediately before inserting the infusion set, break off BLUE Infusion Port Cap with the arrow pointing away from container.

2. Use a non-vented infusion set or close the air-inlet on a vented set.
3. Close the roller clamp of the infusion set.
4. Hold the base of BLUE Infusion Port.
5. Insert spike through BLUE Infusion Port by rotating wrist slightly until the spike is inserted.

NOTE: See full directions accompanying administration set.

WARNING: Do not use flexible container in series connections.

HOW SUPPLIED:

5% Dextrose Injection, USP is supplied in single dose flexible plastic containers as follows:

Product Code	Unit of Sale	Strength	Each
252300	NDC 65219-234-10 Package of 60 **free***flex*®+ bags	2.5 grams per 50 mL (50 mg per mL)	NDC 65219-234-01 50 mL in a 100 mL **free***flex*®+ Bag
262300	NDC 65219-236-10 Package of 50 **free***flex*®+ bags	5 grams per 100 mL (50 mg per mL)	NDC 65219-236-01 100 mL **free***flex*®+ Bag
262325	NDC 65219-238-25 Package of 30 *freeflex*® bags	12.5 grams per 250 mL (50 mg per mL)	NDC 65219-238-01 One 250 mL *freeflex*® bag
262450	NDC 65219-240-50 Package of 20 *freeflex*® bags	25 grams per 500 mL (50 mg per mL)	NDC 65219-240-01 One 500 mL *freeflex*® bag

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

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing.

The container closure is not made with natural rubber latex. Non-PVC, Non-DEHP, Sterile.

Manufactured for:

FRESENIUS KABI

Lake Zurich, IL 60047

www.fresenius-kabi.com/us

Issued: September 2021

PACKAGE LABEL - PRINCIPAL DISPLAY – 5% Dextrose 50 mL Bag Label

free*flex*®+ NDC 65219-234-01

5% Dextrose Injection, USP

2.5 grams per 50 mL

(50 mg per mL)
For intravenous use. Rx only

freeflex®

NDC 65219-234-01

5% Dextrose Injection, USP

2.5 grams per 50 mL
(50 mg per mL)

For intravenous use. Rx only

Each 50 mL contains: Dextrose monohydrate, 2.5 g; water for injection, 50 mL.

252 mOsmol/LITER (CALC.) pH 4.3 (3.2 to 6.5).

Single Dose Only. Discard Unused Portion.

Dextrose solutions without salts should not be used in blood transfusions because of possible Rouleau formation. Additive compatibility, consult pharmacist. When introducing additives, use aseptic technique, mix thoroughly and do not store.

Usual dosage: See package insert.

The overwrap is a moisture barrier.
Use immediately once removed from overwrap.

STORE AT: 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from freezing.

The container closure is not made with natural rubber latex.
Non-PVC, Non-DEHP, Sterile.

LOT

Mfd. for:

FRESENIUS KABI
Lake Zurich, IL 60047
Made in Norway
www.fresenius-kabi.com/us

EXP

403780
FPE 0076 01-69-04-008 1 2 3 4 5 6 7 8 9 0

(01)00365219234012

PACKAGE LABEL - PRINCIPAL DISPLAY – 5% Dextrose 50 mL Case Label

NDC 65219-234-10 252300

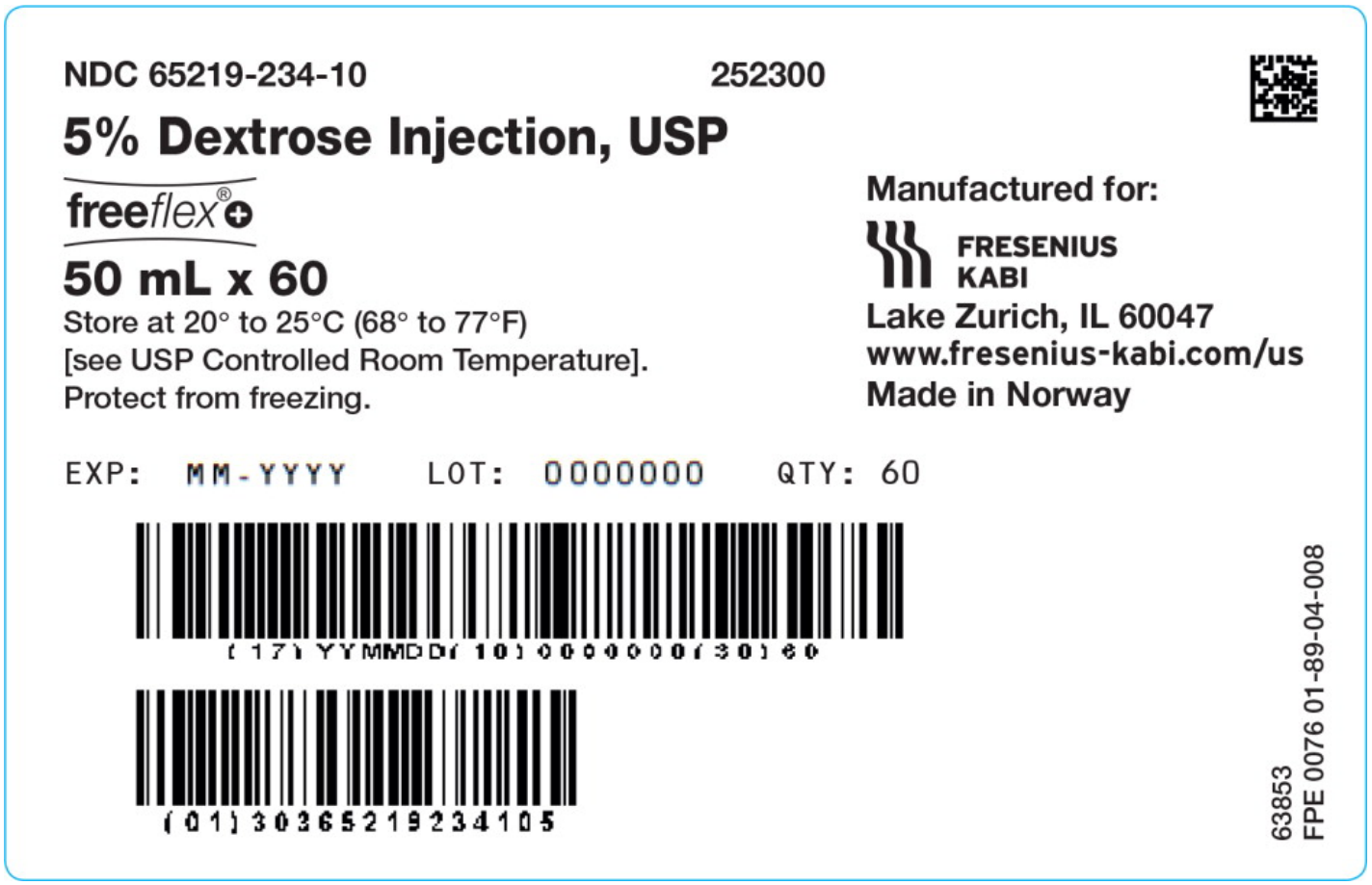
5% Dextrose Injection, USP

50 mL x 60

Store at 20° to 25°C (68° to 77°F)

[see USP Controlled Room Temperature].

Protect from freezing.



PACKAGE LABEL - PRINCIPAL DISPLAY – 5% Dextrose 100 mL Bag Label

free*flex*®+ NDC 65219-236-01

5% Dextrose Injection, USP

5 grams per 100 mL

(50 mg per mL)
For intravenous use. Rx only

freeflex®

NDC 65219-236-01

5% Dextrose Injection, USP

5 grams per 100 mL
(50 mg per mL)

For intravenous use. Rx only

Each 100 mL contains: Dextrose monohydrate, 5 g; water for injection, 100 mL.

252 mOsmol/LITER (CALC.) pH 4.3 (3.2 to 6.5).

Single Dose Only. Discard Unused Portion.

Dextrose solutions without salts should not be used in blood transfusions because of possible Rouleau formation. Additive compatibility, consult pharmacist. When introducing additives, use aseptic technique, mix thoroughly and do not store.

Usual dosage: See package insert.

The overwrap is a moisture barrier.

Use immediately once removed from overwrap.

STORE AT: 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from freezing.

The container closure is not made with natural rubber latex.

Non-PVC, Non-DEHP, Sterile.

LOT

Mfd. for:

FRESENIUS KABI
Lake Zurich, IL 60047
Made in Norway
www.fresenius-kabi.com/us

EXP

403781
FPE 0075 01-69-04-007 1 2 3 4 5 6 7 8 9 0

PACKAGE LABEL - PRINCIPAL DISPLAY – 5% Dextrose 100 mL Case Label

NDC 65219-236-10 262300

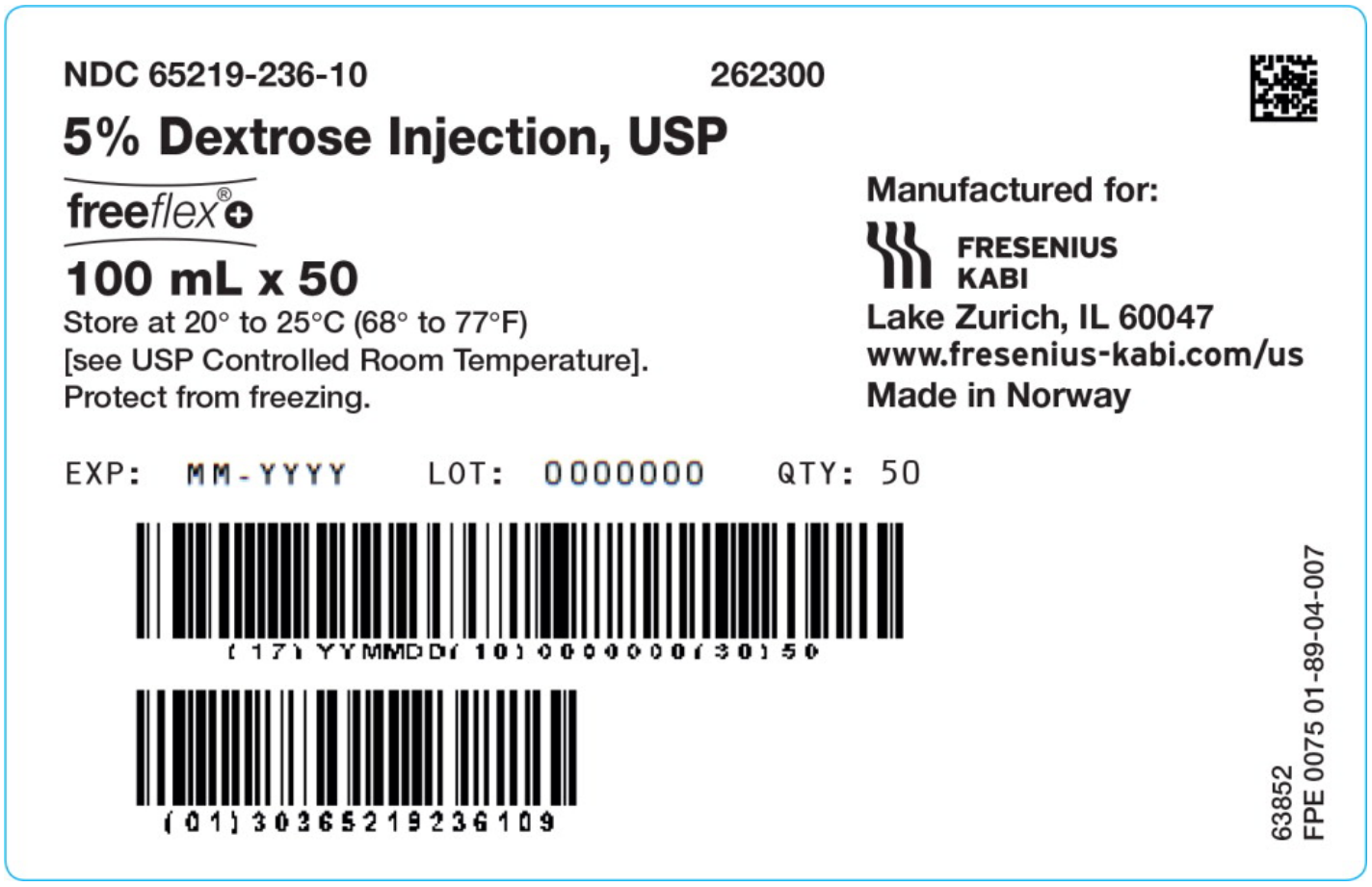
5% Dextrose Injection, USP

100 mL x 50

Store at 20° to 25°C (68° to 77°F)

[see USP Controlled Room Temperature].

Protect from freezing.



PACKAGE LABEL - PRINCIPAL DISPLAY – 5% Dextrose 250 mL Bag Label

NDC 65219-238-01

5% Dextrose Injection, USP

12.5 grams per 250 mL

(50 mg per mL)
For intravenous use. Rx only

NDC 65219-238-01

freeflex®

5% Dextrose Injection, USP

12.5 grams per 250 mL
(50 mg per mL)

50 For intravenous use. Rx only

Each 100 mL contains: Dextrose monohydrate, 5 g; water for injection, 100 mL.

252 mOsmol/LITER (CALC.) pH 4.3 (3.2 to 6.5).

Single Dose Only. Discard Unused Portion.

100 Dextrose solutions without salts should not be used in blood transfusions because of possible Rouleau formation. Additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic technique, mix thoroughly and do not store.

Usual dosage: See package insert.
The overwrap is a moisture barrier.
150 Use immediately once removed from overwrap.

STORE AT: 20° to **25°**C (**68°** to **77°**F) [see USP Controlled Room Temperature]. Protect from freezing.

The container closure is not made with natural rubber latex. Non-PVC, Non-DEHP, Sterile.

PACKAGE LABEL - PRINCIPAL DISPLAY – 5% Dextrose 250 mL Case Label

NDC 65219-238-25 262325

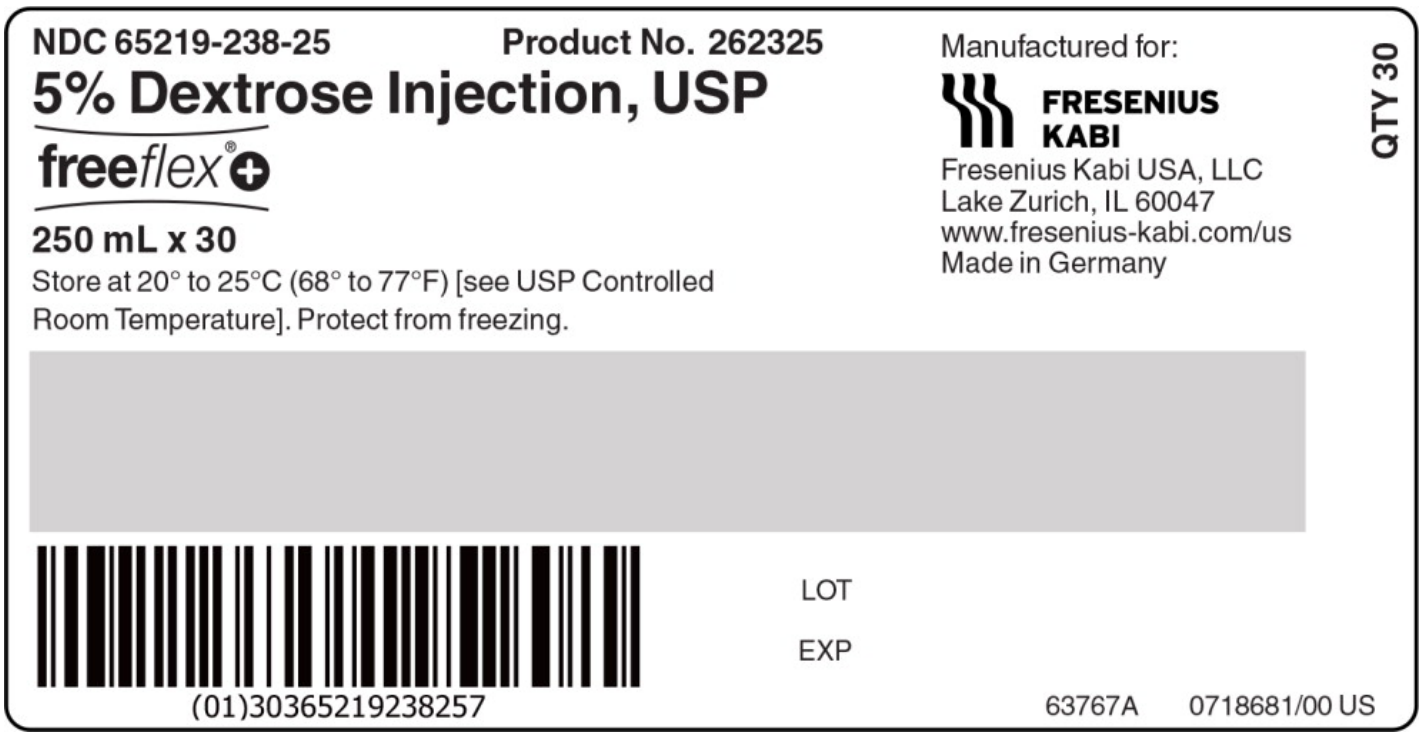
5% Dextrose Injection, USP

250 mL x 30

Store at 20° to 25°C (68° to 77°F)

[see USP Controlled Room Temperature].

Protect from freezing.



PACKAGE LABEL - PRINCIPAL DISPLAY – 5% Dextrose 500 mL Bag Label

NDC 65219-240-01

5% Dextrose Injection, USP

25 grams per 500 mL

(50 mg per mL)
For intravenous use. Rx only

NDC 65219-240-01

freeflex®

5% Dextrose Injection, USP

25 grams per 500 mL
(50 mg per mL)

100 For intravenous use. Rx only

Each 100 mL contains: Dextrose monohydrate, 5 g; water for injection, 100 mL.

252 mOsmol/LITER (CALC.) pH 4.3 (3.2 to 6.5).

Single Dose Only. Discard Unused Portion.

200 Dextrose solutions without salts should not be used in blood transfusions because of possible Rouleau formation. Additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic technique, mix thoroughly and do not store.

Usual dosage: See package insert.

The overwrap is a moisture barrier.

300 Use immediately once removed from overwrap.

STORE AT: 20° to **25°**C (**68°** to **77°**F) [see USP Controlled Room Temperature]. Protect from freezing.

The container closure is not made with natural rubber latex. Non-PVC, Non-DEHP, Sterile.

400

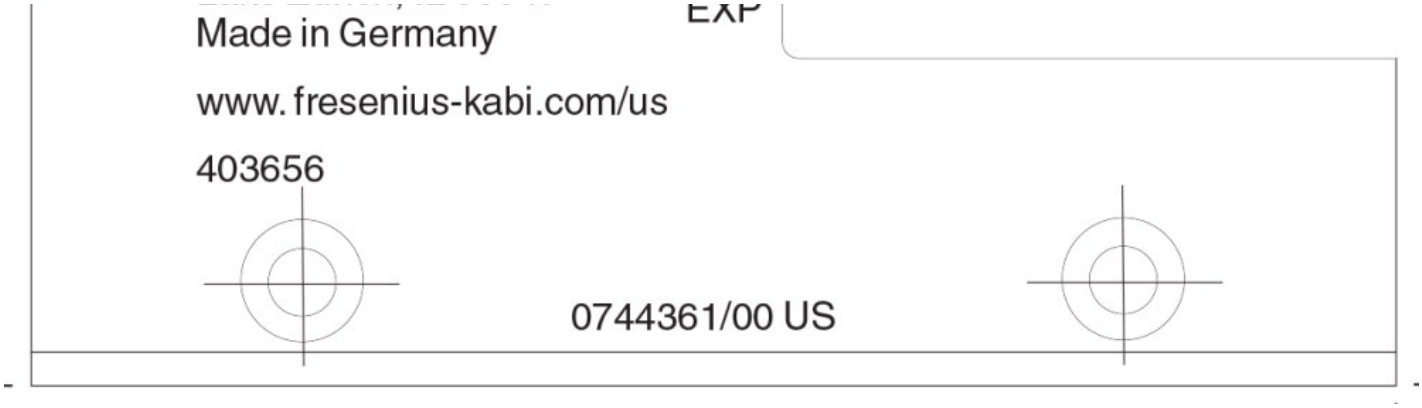
(01)00365219240013

Mfd. for:

FRESENIUS KABI
Lake Zurich, IL 60047

LOT

EXP



PACKAGE LABEL - PRINCIPAL DISPLAY – 5% Dextrose 500 mL Case Label

NDC 65219-240-50 262450

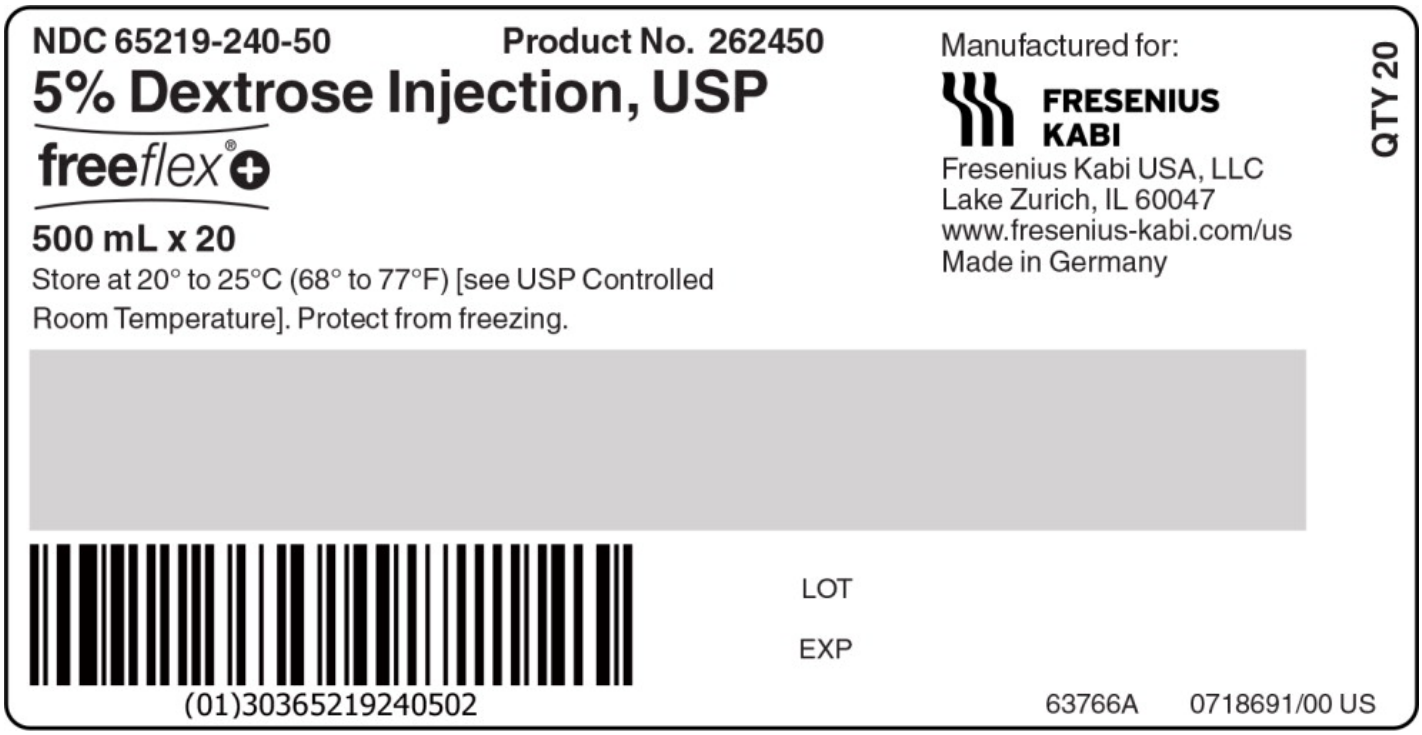
5% Dextrose Injection, USP

500 mL x 20

Store at 20° to 25°C (68° to 77°F)

[see USP Controlled Room Temperature].

Protect from freezing.



DEXTROSE

dextrose monohydrate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-234
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	2500 mg in 50 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65219-234-10	60 in 1 CASE	11/10/2021	
1	NDC:65219-234-01	50 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
ANDA	ANDA207449	10/21/2016	

DEXTROSE

dextrose monohydrate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-236
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	5000 mg in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65219-236-10	50 in 1 CASE	11/10/2021	
1	NDC:65219-236-01	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
ANDA	ANDA207449	10/21/2016	

DEXTROSE

dextrose monohydrate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-238
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	12500 mg in 250 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65219-238-25	30 in 1 CASE	11/10/2021	
1	NDC:65219-238-01	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
ANDA	ANDA207449	10/21/2016	

DEXTROSE

dextrose monohydrate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-240
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	25000 mg in 500 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65219-240-50	20 in 1 CASE	11/10/2021	
1	NDC:65219-240-01	500 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
ANDA	ANDA207449	10/21/2016	

Labeler - Fresenius Kabi USA, LLC (013547657)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi Deutschland GmbH		506719546	ANALYSIS(65219-238, 65219-240) , MANUFACTURE(65219-238, 65219-240)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi Norge AS		731170932	MANUFACTURE(65219-234, 65219-236) , ANALYSIS(65219-234, 65219-236)

Revised: 2/2022 Fresenius Kabi USA, LLC