SODIUM CHLORIDE - sodium chloride injection, solution
Fresenius Kabi USA, LLC

0.45% Sodium Chloride Injection, USP

Rx only

DESCRIPTION:

0.45% Sodium Chloride Injection, USP solution is a sterile and nonpyrogenic solution intended for intravenous administration.

Each 100 mL of 0.45% Sodium Chloride Injection, USP contains 450 mg sodium chloride in water for injection. Electrolytes per 1,000 mL: sodium 77 mEq; chloride 77 mEq. The osmolarity is 154 mOsmol/L (calc.).

The pH in the 100 mL and smaller containers is 6.0; for the 250 mL and larger containers, the pH is 5.6. The pH range is 4.5 to 7.0 for all containers.

The 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.

0.45% Sodium Chloride Injection, USP is a parenteral fluid and electrolyte replenisher.

Sodium chloride, USP is chemically designated NaCl, a white crystalline powder freely soluble in water.

Water for Injection, USP is chemically designated H_2O.

The flexible plastic 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 electrolytes.

Solutions which provide combinations of hypotonic or isotonic concentrations of sodium chloride are suitable for parenteral maintenance or replacement of water and electrolyte requirements.

Isotonic concentrations of sodium chloride are suitable for parenteral replacement of chloride losses that exceed or equal the sodium loss. Hypotonic concentrations of sodium chloride are suited for parenteral maintenance of water requirements when only small quantities of salt are desired. A hypertonic concentration of sodium chloride may be used to repair severe salt depletion syndrome.

Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) ions. Sodium (Na^+) is the principal cation of the extracellular fluid and plays a large part in the therapy of fluid and electrolyte disturbances. Chloride (Cl^-) has an integral role in buffering action when oxygen and carbon dioxide exchange occurs in the red blood cells. The distribution and excretion of sodium (Na^+) and chloride (Cl^-) are largely under the control of the kidney which maintains a balance between intake and output.

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.

INDICATIONS AND USAGE:

Intravenous solutions containing sodium chloride are indicated for parenteral replenishment of fluid and sodium chloride as required by the clinical condition of the patient.

CONTRAINDICATIONS:

None known.

WARNINGS:

0.45% Sodium chloride injection should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention.

The intravenous administration of 0.45% Sodium chloride injection can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

The risk of dilutive states is inversely proportional to the electrolyte concentration of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

In patients with diminished renal function, administration of 0.45% Sodium chloride injection may result in sodium retention.

PRECAUTIONS:

General

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Laboratory Tests

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.

Drug Interactions

Caution must be exercised in the administration of 0.45% Sodium chloride injection to patients receiving corticosteroids or corticotropin.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies have not been performed with 0.45% Sodium chloride injection to evaluate the potential for carcinogenesis, mutagenesis or impairment of fertility.

Pregnancy

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with 0.45% Sodium chloride injection. It is also not known whether 0.45% Sodium chloride injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 0.45% Sodium chloride injection should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of 0.45% Sodium chloride injection on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

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 0.45% Sodium chloride injection is administered to a nursing mother.

Pediatric Use

The use of 0.45% Sodium chloride injection in pediatric patients is based on clinical practice.

Plasma electrolyte concentrations should be closely monitored in the pediatric population as this population may have impaired ability to regulate fluids and electrolytes.

The infusion of hypotonic fluids (0.45% Sodium chloride injection) together with the non-osmotic secretion of ADH may result in hyponatremia in patients with acute volume depletion. Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema and death, therefore acute symptomatic hyponatremic encephalopathy is considered a medical emergency.

Geriatric Use

Clinical studies of 0.45% Sodium chloride injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses 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 drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

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

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.

In addition to the above listed adverse reactions hyponatremia has been reported for 0.45% Sodium chloride injection (see ***Pediatric Use***).

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.

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.

The flexible container is fabricated from a specially formulated non-plasticized, film containing polypropylene and thermoplastic elastomers (**free***flex*® bag). 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.

HOW SUPPLIED:

0.45% Sodium Chloride Injection, USP is supplied in single-dose flexible plastic containers as follows:

Product Code	**Unit of Sale**	**Strength**	**Each**
242250	NDC 65219-226-50 Package of 60 **free***flex*®+ bags	0.225 grams per 50 mL (4.5 mg per mL)	NDC 65219-226-01 50 mL in a 100 mL **free***flex*® + bag
242200	NDC 65219-228-10 Package of 50 **free***flex*®+ bags	0.45 grams per 100 mL (4.5 mg per mL)	NDC 65219-228-01 100 mL **free***flex*®+ bag
242325	65219-230-25 Package of 30	1.125 grams per 250 mL (4.5 mg per mL)	65219-230-01 250 mL in a 250 mL **free***flex*® bag
242350	65219-232-50 Package of 20	2.25 grams per 500 mL (4.5 mg per mL)	65219-232-01 500 mL in a 500 mL **free***flex*® bag

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.

Manufactured for:

FRESENIUS KABI

Lake Zurich, IL 60047

www.fresenius-kabi.com/us

Issued: October 2021

PACKAGE LABEL - PRINCIPAL DISPLAY – 0.45% Sodium Chloride 50 mL Bag Label

NDC 65219-226-01 **50 mL**
0.45% Sodium Chloride Injection, USP

0.225 grams per 50 mL

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

freeflex®

NDC 65219-226-01

50 mL

0.45% Sodium Chloride Injection, USP

0.225 grams per 50 mL
(4.5 mg per mL)

For intravenous use. Rx only

Each 100 mL contains: Sodium Chloride
450 mg in water for injection.

Electrolytes per 1,000 mL:

Sodium	77 mEq
Chloride	77 mEq
154 mOsmol/LITER (CALC.)	pH 6.0 (4.5 to 7.0)

Single-Dose Container. Discard Unused Portion.

Additives may be incompatible. Consult with pharmacist, if available. 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.

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

LOT

EXP

403785
FPE 1340 01-69-19-016 1234567890

(01)00365219226017

PACKAGE LABEL - PRINCIPAL DISPLAY – 0.45% Sodium Chloride 50 mL Case Label

NDC 65219-226-50 242250

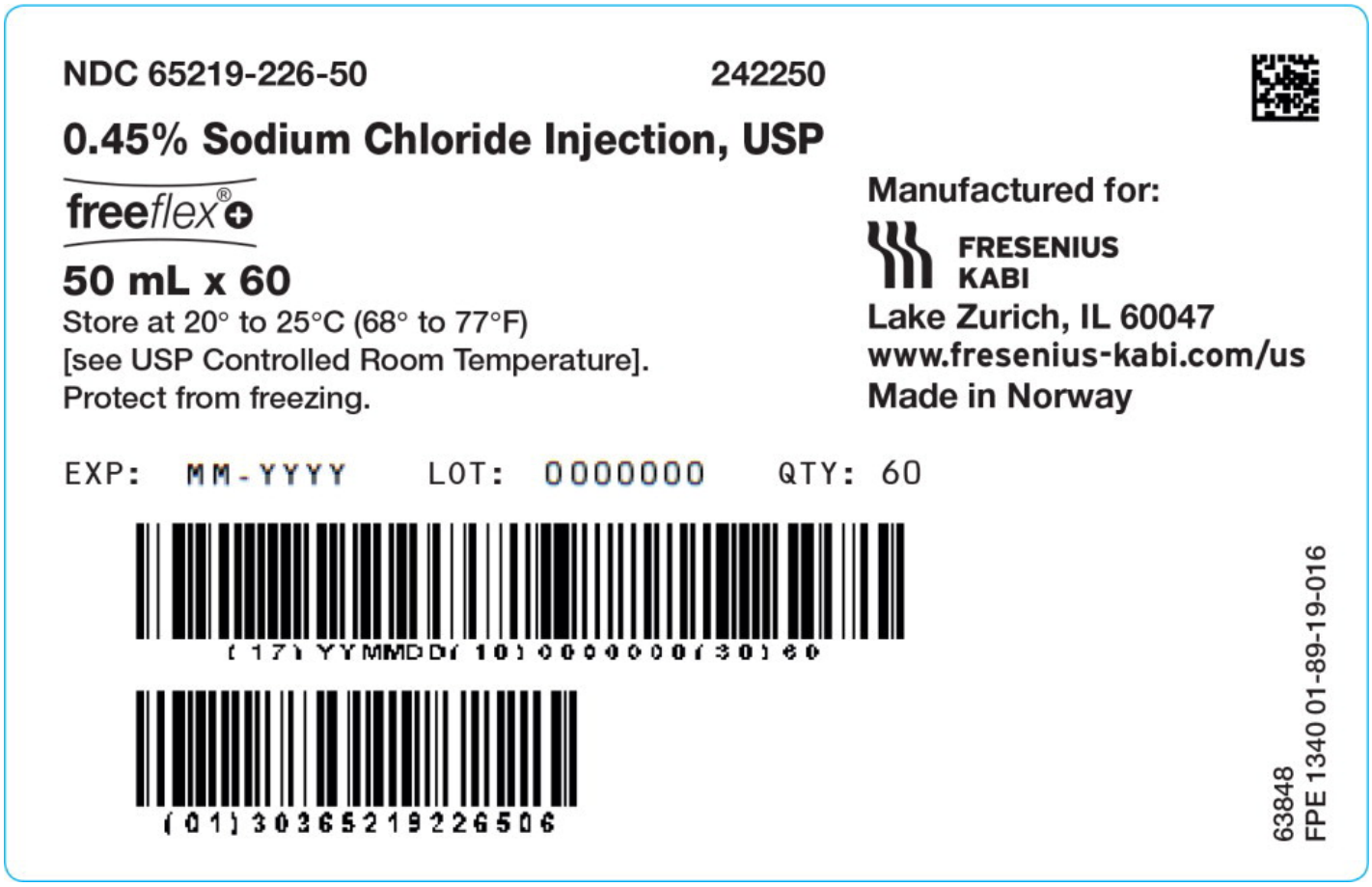
0.45% Sodium Chloride Injection, USP

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 – 0.45% Sodium Chloride 100 mL Bag Label

NDC 65219-228-01 **100 mL**
0.45% Sodium Chloride Injection, USP

0.45 grams per 100 mL

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

freeflex®

NDC 65219-228-01

100 mL

0.45% Sodium Chloride Injection, USP

0.45 grams per 100 mL
(4.5 mg per mL)

For intravenous use. Rx only

Each 100 mL contains: Sodium Chloride
450 mg in water for injection.

Electrolytes per 1,000 mL:

Sodium	77 mEq
Chloride	77 mEq
154 mOsmol/LITER (CALC.)	pH 6.0 (4.5 to 7.0)

Single-Dose Container. Discard Unused Portion.

Additives may be incompatible. Consult with pharmacist, if available. 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.

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

LOT

EXP

403784
FPE 1341 01-69-19-017 1234567890

(01)00365219228011

PACKAGE LABEL - PRINCIPAL DISPLAY – 0.45% Sodium Chloride 100 mL Case Label

NDC 65219-228-10 242200

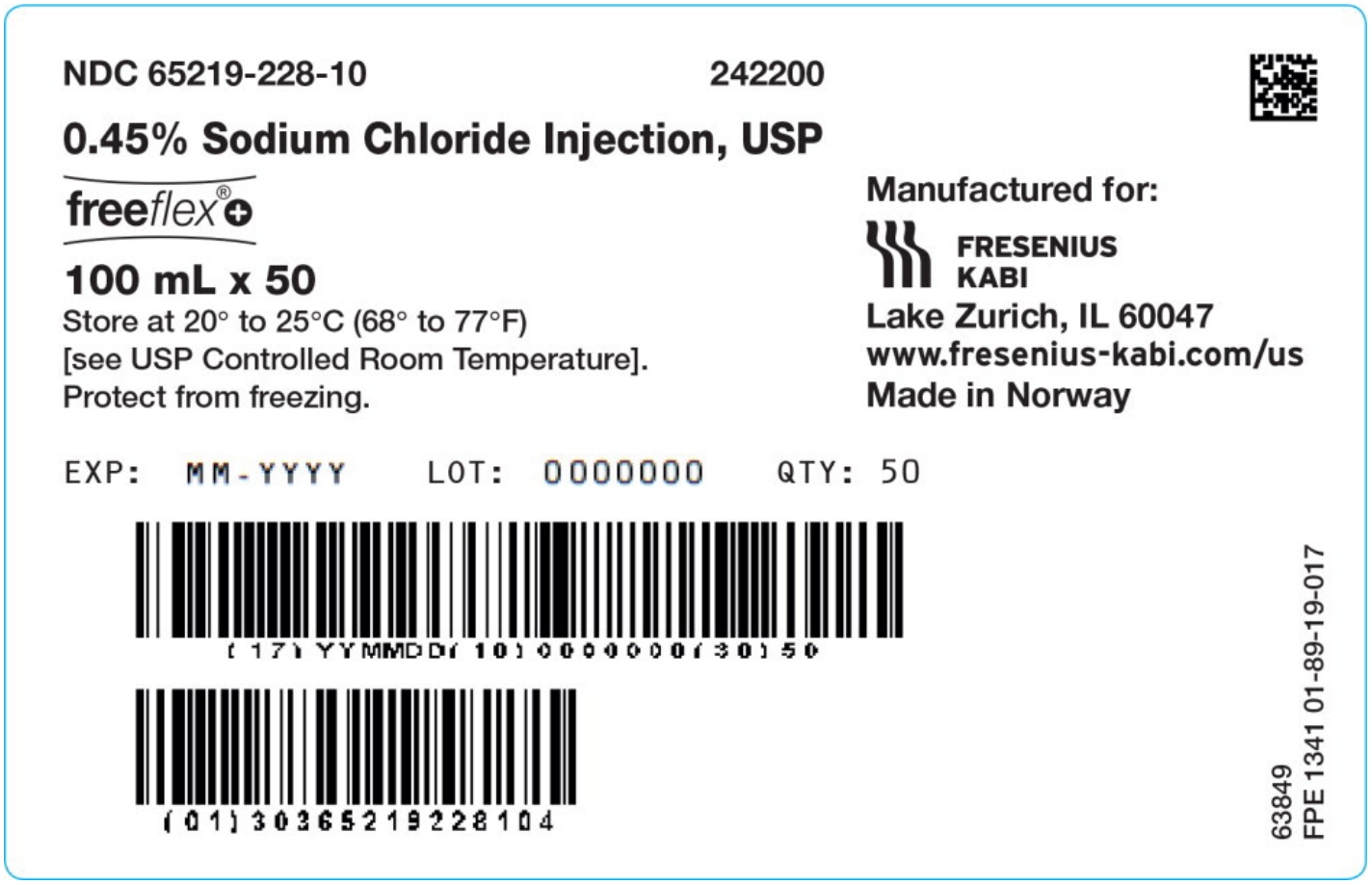
0.45% Sodium Chloride Injection, USP

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 – 0.45% Sodium Chloride 250 mL Bag Label

NDC 65219-230-01 **250 mL**
0.45% Sodium Chloride Injection, USP

1.125 grams per 250 mL

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

NDC 65219-230-01

freeflex®

250 mL

0.45% Sodium Chloride Injection, USP

1.125 grams per 250 mL
(4.5 mg per mL)

For intravenous use. Rx only

50

Each 100 mL contains: Sodium Chloride 450 mg in water for injection.

Electrolytes per 1,000 mL:

Sodium	77 mEq
Chloride	77 mEq

154 mOsmol/LITER (CALC.) pH 5.6 (4.5 to 7.0)

100

Single-Dose Container. Discard Unused Portion.

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

Usual dosage: See package insert.

150

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.

PACKAGE LABEL - PRINCIPAL DISPLAY – 0.45% Sodium Chloride 250 mL Case Label

NDC 65219-230-25 242325

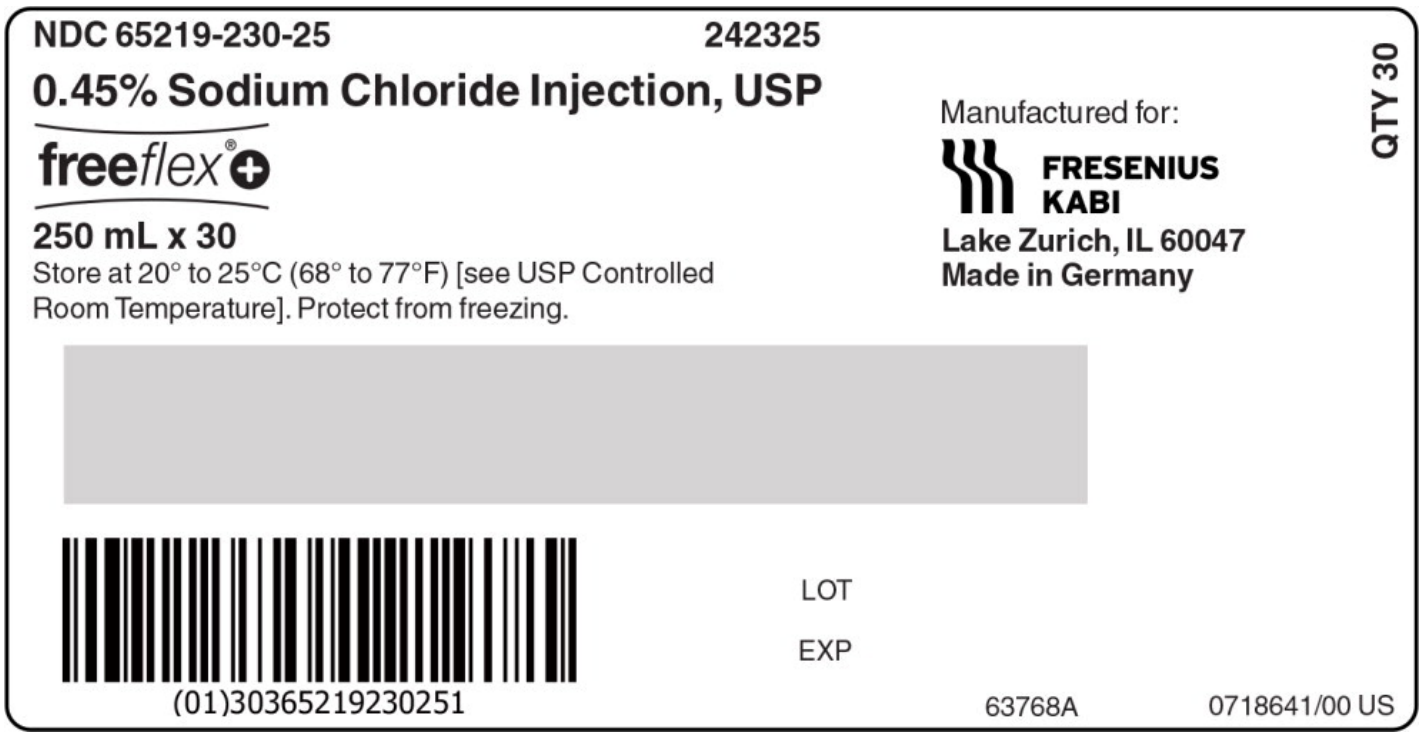
0.45% Sodium Chloride Injection, USP

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 – 0.45% Sodium Chloride 500 mL Bag Label

NDC 65219-232-01 **500 mL**
0.45% Sodium Chloride Injection, USP

2.25 grams per 500 mL

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

NDC 65219-232-01

freeflex®

500 mL

0.45% Sodium Chloride Injection, USP

2.25 grams per 500 mL
(4.5 mg per mL)

For intravenous use. Rx only

100

Each 100 mL contains: Sodium Chloride 450 mg in water for injection.

Electrolytes per 1,000 mL:	
Sodium	77 mEq
Chloride	77 mEq
154 mOsmol/LITER (CALC.)	pH 5.6 (4.5 to 7.0)

200

Single-Dose Container. Discard Unused Portion.

Additives may be incompatible. Consult with pharmacist, if available. 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.

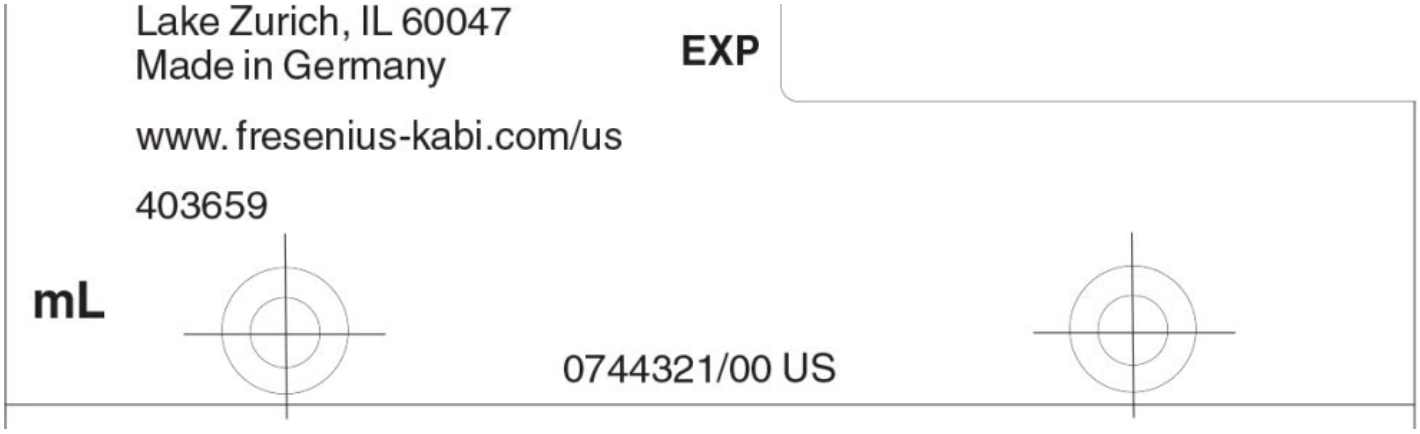
400

(01)00365219232018

Mfd. for:

FRESENIUS KABI

LOT



PACKAGE LABEL - PRINCIPAL DISPLAY – 0.45% Sodium Chloride 500 mL Case Label

NDC 65219-232-50 242350

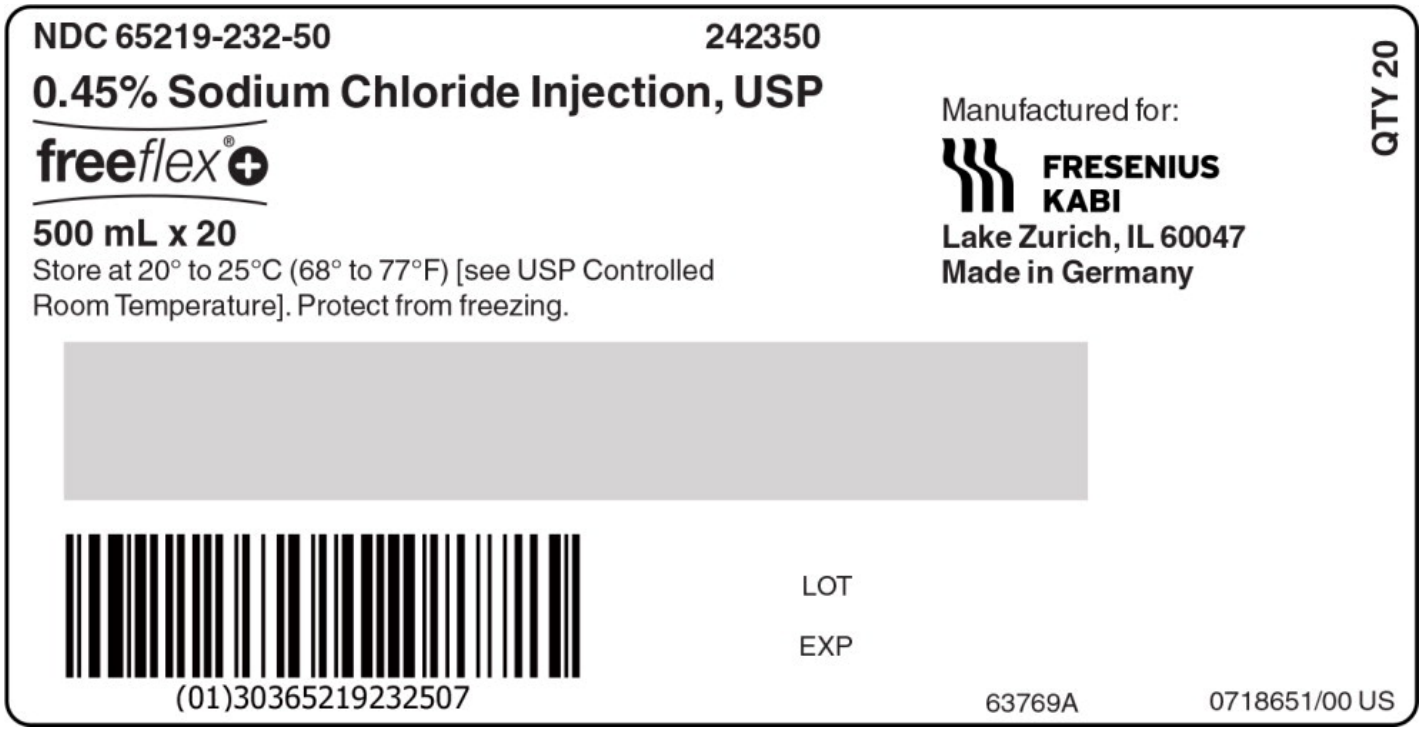
0.45% Sodium Chloride Injection, USP

500 mL x 20

Store at 20° to 25°C (68° to 77°F)

[see USP Controlled Room Temperature].

Protect from freezing.



SODIUM CHLORIDE
sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-226
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	225 mg in 50 mL

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65219-226-50	60 in 1 CASE	11/30/2021	
1	NDC:65219-226-01	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	ANDA208122	07/23/2018	

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-228
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	450 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65219-228-10	50 in 1 CASE	11/30/2021	
1	NDC:65219-228-01	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	ANDA208122	07/23/2018	

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-230
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	1125 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:65219-230-25	30 in 1 CASE	11/30/2021	
1	NDC:65219-230-01	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	ANDA208122	07/23/2018	

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-232
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	2250 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:65219-232-50	20 in 1 CASE	11/30/2021	
1	NDC:65219-232-01	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	ANDA208122	07/23/2018	

Labeler - Fresenius Kabi USA, LLC (013547657)

Establishment

Name	Address	ID/FEI	Business Operations
UP Halden			ANALYSIS(65219-226, 65219-228, 65219-230, 65219-232) , MANUFACTURE(65219-

HP Halden Pharma AS		347747373	226, 65219-228, 65219-230, 65219-232) , PACK(65219-226, 65219-228, 65219-230, 65219-232)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi Deutschland GmbH		506719546	ANALYSIS(65219-226, 65219-228, 65219-230, 65219-232) , MANUFACTURE(65219-226, 65219-228, 65219-230, 65219-232)

Revised: 5/2024

Fresenius Kabi USA, LLC