B. BRAUN MEDICAL INC.
861 Marcon Blvd.
Allentown, PA 18109
Telephone: (844) 903-6417
Fax: (610) 849-1197
E-mail: recalls@bbraunusa.com

November 20, 2024

IMPORTANT DRUG INFORMATION

Subject: Overwrap Defects in Certain Lots of B. Braun Medical Inc.'s FDA-Approved 0.9% Sodium Chloride Injection, USP in the EXCEL® Plus container, 1000 mL, NDC 0264-5802-00

Dear Healthcare Provider:

The purpose of this letter is to inform you of important information for certain lots of 0.9% Sodium Chloride Injection, USP in the EXCEL® Plus container, 1000 mL. To address the current drug shortage, B. Braun Medical Inc. is coordinating with the U.S. Food and Drug Administration (FDA) to release the eight (8) lots listed below with overwrap defects. Specifically, the following lots are impacted:

Product Code	NDC	Description	Lot Number	Expiration Date
Q8000	0264-5802-00	0.9% Sodium Chloride USP in the EXCEL® Plus container, 1000 mL	0061932735	30.Sep.2026
Q8000	0264-5802-00	0.9% Sodium Chloride USP in the EXCEL® Plus container, 1000 mL	0061948445	31.Dec.2026
Q8000	0264-5802-00	0.9% Sodium Chloride USP in the EXCEL® Plus container, 1000 mL	0061924451	30.Jun.2026
Q8000	0264-5802-00	0.9% Sodium Chloride USP in the EXCEL® Plus container, 1000 mL	0061948440	31.Dec.2026
Q8000	0264-5802-00	0.9% Sodium Chloride USP in the EXCEL® Plus container, 1000 mL	0061948446	31.Dec.2026
Q8000	0264-5802-00	0.9% Sodium Chloride USP in the EXCEL® Plus container, 1000 mL	0061955473	31.Jan.2027
Q8000	0264-5802-00	0.9% Sodium Chloride USP in the EXCEL® Plus container, 1000 mL	0061964194	31.Mar.2027
Q8000	0264-5802-00	0.9% Sodium Chloride USP in the EXCEL® Plus container, 1000 mL	0061965608	31.Mar.2027

Description of the Overwrap Defects:

Per the established product specifications, the overwrap is to remain intact with no holes, tears, or separated welds exceeding 0.5 inches. During inspection of these lots, the overwrap is intact on the product but some units may not be completely sealed. The typical defect is an opening in the transverse weld (the weld that seals the overwrap closed over both ends of the bags) that is about 1 inch in length. The solution container itself meets all established specifications for integrity and sterility. (Refer to Figure 1 below.)

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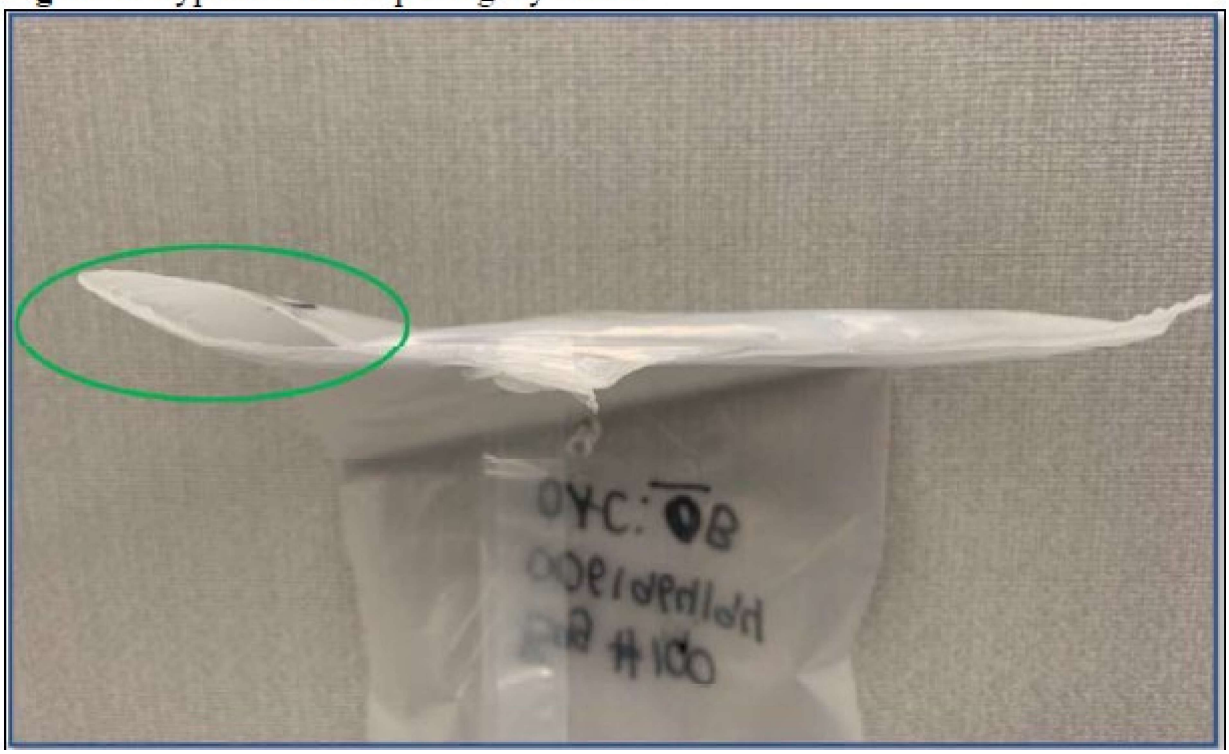
Figure 1. Typical overwrap integrity defect



Risks Associated with Use of the Impacted Product

The function of the product overwrap is to limit water vapor transfer that may affect the potency of the product and the total volume of fluid inside the container throughout the product shelf-life. It is important to note that containers are overfilled. Testing was conducted to evaluate the worst-case condition of completely missing overwrap. These studies found that the product is still meeting the potency and the total volume specification.

No units with completely missing overwrap have been identified in the affected lots (only small openings as indicated in the section above) which makes the potential increase of potency and volume loss less than the aforementioned worst-case condition. All other product release criteria for these lots have been met (e.g. potency, sterility, etc.) in accordance with the USP monograph. Therefore, the risks of using this product on patients is negligible.

Recommended Actions:

Although we do not expect any impact on the product quality, if an opening in the overwrap is encountered during use with the affected lots, follow the product instructions for use:

- Check for minute leaks by squeezing solution container firmly. If leaks are found, discard solution as sterility may be impaired.
- Invert container and carefully inspect the solution in good light for cloudiness, haze, or particulate matter. Any container which is suspect should not be used.
- Use only if solution is clear and container and seals are intact.

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If there are no indications of integrity or sterility failures in the primary container then the solution may be administered to patients. Scanning of barcoded information is not affected by this issue.

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events in patients receiving 0.9% Sodium Chloride USP in the EXCEL® Plus container, 1000 mL to B. Braun at 1-833-425-1464.

Additionally, adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Complete and submit the report Online: www.fda.gov/medwatch/report.htm

Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

You may also contact our Medical Affairs Department at 1-800-854-6851 if you have any questions about the information contained in this letter for the safe and effective use of 0.9% Sodium Chloride USP in the EXCEL® Plus container, 1000 mL.

Sincerely,

Electronically signed by: Jonathan Severino
Reason: For the reason(s) specified in the document.
Date: Nov 20, 2024 17:49 EST

Jonathan Severino
Director, Postmarket Surveillance
B. Braun Medical Inc.

Enclosure(s): 0.9% Sodium Chloride USP in the EXCEL® Plus container, 1000 mL Full Prescribing Information

Sodium Chloride Injections USP

DESCRIPTION

Each 100 mL of **0.9% Sodium Chloride Injection USP** contains:

Sodium Chloride USP 0.9 g; Water for Injection USP qs
pH: 5.6 (4.5–7.0) Calculated Osmolarity: 308 mOsmol/liter
pH adjusted with Hydrochloric Acid NF
Concentration of Electrolytes (mEq/liter): Sodium 154 Chloride 154

Each 100 mL of **0.45% Sodium Chloride Injection USP** contains:

Sodium Chloride USP 0.45 g; Water for Injection USP qs
pH: 5.6 (4.5–7.0) Calculated Osmolarity: 154 mOsmol/liter, hypotonic
pH adjusted with Hydrochloric Acid NF
Concentration of Electrolytes (mEq/liter): Sodium 77 Chloride 77

Sodium Chloride Injections USP are sterile, nonpyrogenic, isotonic and contain no bacteriostatic or antimicrobial agents.

The formula of the active ingredient is:

Ingredient	Molecular Formula	Molecular Weight
Sodium Chloride USP	NaCl	58.44

Not made with natural rubber latex, PVC or DEHP.

The plastic container is made from a multilayered film specifically developed for parenteral drugs. It contains no plasticizers and exhibits virtually no leachables. The solution contact layer is a rubberized copolymer of ethylene and propylene. The container is nontoxic and biologically inert. The container-solution unit is a closed system and is not dependent upon entry of external air during administration. The container is overwrapped to provide protection from the physical environment and to provide an additional moisture barrier when necessary.

Addition of medication should be accomplished using complete aseptic technique.

The closure system has two ports; the one for the administration set has a tamper evident plastic protector and the other is a medication addition site. Refer to the Directions for Use of the container.

CLINICAL PHARMACOLOGY

Sodium Chloride Injections USP provide electrolytes and are a source of water for hydration. They are capable of inducing diuresis depending on the clinical condition of the patient.

Sodium, the major cation of the extracellular fluid, functions primarily in the control of water distribution, fluid balance, and osmotic pressure of body fluids. Sodium is also associated with chloride and bicarbonate in the regulation of the acid-base equilibrium of body fluid.

Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.

INDICATIONS AND USAGE

These intravenous solutions are indicated for use in adults and pediatric patients as sources of electrolytes and water for hydration.

0.9% Sodium Chloride Injection USP is indicated for extracellular fluid replacement, treatment of metabolic alkalosis in the presence of fluid loss and mild sodium depletion.

0.9% Sodium Chloride Injection USP is also indicated for use as a priming solution in hemodialysis procedures and may be used to initiate and terminate blood transfusions without hemolyzing red blood cells.

0.45% Sodium Chloride Injection USP is primarily a hydrating solution and may be used to assess the status of the kidneys, since more water is provided than is required for excretion of salt. It may also be used in the treatment of hyperosmolar diabetes where the use of dextrose is inadvisable and there is a need for large amounts of fluid without an excess of sodium ions.

Sodium Chloride Injections USP are also indicated as pharmaceutic aids and diluents for the infusion of compatible drug additives. Refer to prescribing information accompanying additive drugs.

CONTRAINDICATIONS

These solutions are contraindicated where the administration of sodium or chloride could be clinically detrimental.

WARNINGS

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentration. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

Solutions containing sodium ions 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 is sodium retention with edema. In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention.

Infusion of isotonic (0.9%) sodium chloride during or immediately after surgery may result in excessive sodium retention. Use the patient's circulatory system status as a guide.

PRECAUTIONS

General

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. Significant deviations from normal concentrations may require tailoring of the electrolyte pattern, in these or alternative solutions.

These solutions should be used with care in patients with hypervolemia, renal insufficiency, urinary tract obstruction, or impending or frank cardiac decompensation.

Extraordinary electrolyte losses such as may occur during protracted nasogastric suction, vomiting, diarrhea or gastrointestinal fistula drainage may necessitate additional electrolyte supplementation.

Additional essential electrolytes, minerals and vitamins should be supplied as needed.

Sodium-containing solutions should be administered with caution to patients receiving corticosteroids or corticotropin, or to other salt-retaining patients. Care should be exercised in administering solutions containing

sodium to patients with renal or cardiovascular insufficiency, with or without congestive heart failure, particularly if they are postoperative or elderly.

Infusion of more than one liter of isotonic (0.9%) sodium chloride per day may supply more sodium and chloride than normally found in serum, and can exceed normal tolerance, resulting in hypernatremia; this may also cause a loss of bicarbonate ions, resulting in an acidifying effect.

To minimize the risk of possible incompatibilities arising from mixing this solution with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration and periodically during administration.

Do not use plastic containers in series connection.

If administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result. If administration is not controlled by a pumping device, refrain from applying excessive pressure (>300mmHg) causing distortion to the container such as wringing or twisting. Such handling could result in breakage of the container.

These solutions are intended for intravenous administration using sterile equipment. It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Use only if solution is clear and container and seals are intact.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with Sodium Chloride Injections USP have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Pregnancy:

Teratogenic Effects

Animal reproduction studies have not been conducted with Sodium Chloride Injections USP. It is also not known whether Sodium Chloride Injections USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chloride Injections USP 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 Sodium Chloride Injections USP are administered to a nursing woman.

Pediatric Use

Safety and effectiveness of sodium chloride injections in pediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

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.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions 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.

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. Anaphylaxis has occasionally been reported.

The physician should also be alert to the possibility of adverse reactions to drug additives. Prescribing information for drug additives to be administered in this manner should be consulted.

Symptoms may result from an excess or deficit of one or more of the ions present in the solution; therefore, frequent monitoring of electrolyte levels is essential.

Hypernatremia may be associated with edema and exacerbation of congestive heart failure due to the retention of water, resulting in an expanded extracellular fluid volume. Cerebral edema and myelinolysis have been reported.

If infused in large amounts, chloride ions may cause a loss of bicarbonate ions, resulting in an acidifying effect.

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 a fluid or solute overload during parenteral therapy, reevaluate the patient's condition and institute appropriate corrective treatment.

DOSAGE AND ADMINISTRATION

These solutions are for intravenous use only.

Dosage is to be directed by a physician and is dependent upon age, weight, clinical condition of the patient and laboratory determinations. Frequent laboratory determinations and clinical evaluation are essential to monitor changes in blood glucose and electrolyte concentrations, and fluid and electrolyte balance during prolonged parenteral therapy.

In the average adult, daily requirements of sodium and chloride are met by the infusion of one liter of 0.9% sodium chloride (154 mEq each of sodium and chloride).

There is no specific pediatric dose. The dose is dependent on weight, clinical condition and laboratory results. Follow recommendations of appropriate pediatric reference text. (See **PRECAUTIONS, *Pediatric Use***.)

Fluid administration should be based on calculated maintenance or replacement fluid requirements for each patient.

0.9% Sodium Chloride Injection USP may also be administered intravascularly as a priming fluid in hemodialysis procedures.

When Sodium Chloride Injections USP are used as diluents for infusion of compatible drug additives, refer to dosage and administration information accompanying additive drugs.

Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

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

HOW SUPPLIED

Sodium Chloride Injections USP are supplied sterile and nonpyrogenic in EXCEL® Plus Containers. The 1000 mL containers are packaged 12 per case; the 500 mL containers are packaged 24 per case.

NDC	REF	Size
0.9% Sodium Chloride Injection USP		
0264-5802-00	Q8000	1000 mL
0264-5802-10	Q8001	500 mL
0.45% Sodium Chloride Injection USP		
0264-5804-00	Q8020	1000 mL

Store at 20 to 25°C (68 to 77°F); excursions permitted 15 to 30°C (59 to 86°F). [See USP Controlled Room Temperature.]

Avoid excessive heat. Protect from freezing.

Rx only

Revised: September 2019
EXCEL is a registered trademark of B. Braun Medical Inc.

Directions for Use of EXCEL® Plus Container

Caution: Do not use plastic containers in series connection.

To Open

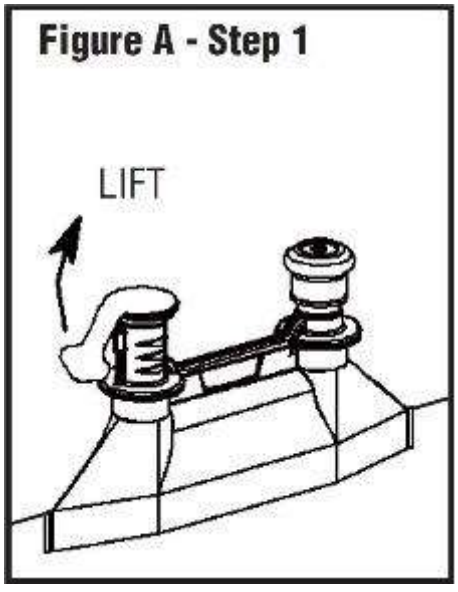
Tear overwrap down at notch and remove solution container. Check for minute leaks by squeezing solution container firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below before preparing for administration.

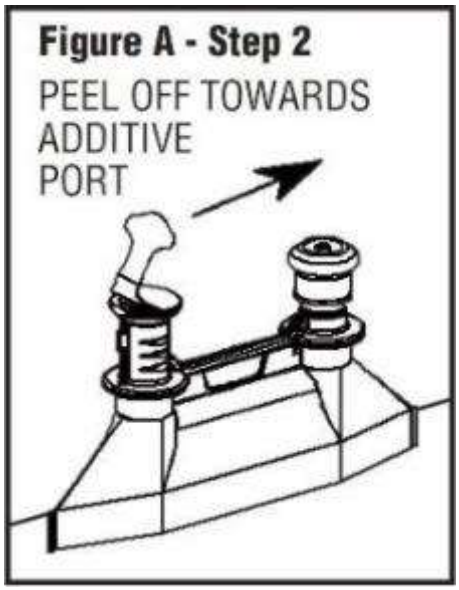
NOTE: Before use, perform the following checks:

- Inspect each container. Read the label. Ensure solution is the one ordered and is within the expiration date.
- Invert container and carefully inspect the solution in good light for cloudiness, haze, or particulate matter. Any container which is suspect should not be used.
- Use only if solution is clear and container and seals are intact.

Preparation for Administration

1. Remove foil cover from sterile set port at bottom of container as shown in **Figure A, Steps 1 and 2.**





2. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Warning: Some additives may be incompatible.

To Add Medication Before Solution Administration

1. Prepare medication site.
2. Using syringe with 18–22 gauge needle, puncture medication port and inner diaphragm and inject.
3. Squeeze and tap ports while ports are upright and mix solution and medication thoroughly.

To Add Medication During Solution Administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 18–22 gauge needle of appropriate length (at least 5/8 inch), puncture resealable medication port and inner diaphragm and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by tapping and squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862

Y36-002-932 LD-629-1

PRINCIPAL DISPLAY PANEL - 0.9 g/1000 mL Container Label

0.9% Sodium Chloride
Injection USP

REF Q8000
NDC 0264-5802-00

1000 mL
EXCEL® PLUS CONTAINER

Each 100 mL contains: Sodium Chloride USP 0.9 g;
Water for Injection USP qs

pH adjusted with HCl NF
pH: 5.6 (4.5-7.0); Calc. Osmolarity: 308 mOsmol/liter

Electrolytes (mEq/liter): Na^+ 154; Cl^- 154

Sterile, nonpyrogenic. Single-dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Store at 20 to 25°C (68 to 77°F); excursions permitted 15 to 30°C (59 to 86°F). [See USP Controlled Room Temperature.]

Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

Rx only

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Bethlehem, PA 18018-3524 USA
1-800-227-2862

Y94-003-357
LD-630-1

EXP
LOT

0.9% Sodium Chloride Injection USP

REF Q8000
NDC 0264-5802-00

1000 mL
EXCEL® PLUS CONTAINER

-0-

-1-

Each 100 mL contains: Sodium Chloride USP 0.9 g; Water for Injection USP qs

pH adjusted with HCl NF
pH: 5.6 (4.5-7.0); Calc. Osmolarity: 308 mOsmol/liter

-2-

Electrolytes (mEq/liter): Na^+ 154; Cl^- 154

-3-

Sterile, nonpyrogenic. Single-dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

2D CODE

-4-

WARNINGS: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

-5-

Store at 20 to 25°C (68 to 77°F); excursions permitted 15 to 30°C (59 to 86°F). [See USP Controlled Room Temperature.]

Avoid excessive heat. Protect from freezing. See Package Insert.

-6-

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

-7-

Not made with natural rubber latex, PVC or DEHP.

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Rx only

7 OTHER

PRINCIPAL DISPLAY PANEL - 0.9 g/500 mL Container Label

0.9% Sodium Chloride
Injection USP

REF Q8001
NDC 0264-5802-10

500 mL
EXCEL® PLUS CONTAINER

Each 100 mL contains: Sodium Chloride USP 0.9 g;
Water for Injection USP qs

pH adjusted with HCl NF
pH: 5.6 (4.5–7.0); Calc. Osmolarity: 308 mOsmol/liter

Electrolytes (mEq/liter): Na^+ 154; Cl^- 154

Sterile, nonpyrogenic. Single-dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Store at 20 to 25°C (68 to 77°F); excursions permitted 15 to 30°C (59 to 86°F). [See USP Controlled Room Temperature.]

Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

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Bethlehem, PA 18018-3524 USA
1-800-227-2862

Y94-003-358
LD-631-1

EXP
LOT

0.9% Sodium Chloride Injection USP

REF Q8001
NDC 0264-5802-10

500 mL
EXCEL® PLUS CONTAINER

-0-

Each 100 mL contains: Sodium Chloride USP 0.9 g;
Water for Injection USP qs

pH adjusted with HCl NF
pH: 5.6 (4.5-7.0); Calc. Osmolarity: 308 mOsmol/liter

Electrolytes (mEq/liter): Na^+ 154; Cl^- 154

2D CODE

-1-

Sterile, nonpyrogenic. Single-dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

-2-

Store at 20 to 25°C (68 to 77°F); excursions permitted 15 to 30°C (59 to 86°F). [See USP Controlled Room Temperature.]

Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

Rx only

7 OTHER

-3-

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B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862

BARCODE

-4-

BARCODE

Y94-003-358
LD-631-1

EXP LOT

PRINCIPAL DISPLAY PANEL - 0.45 g/1000 mL Container Label

0.45% Sodium Chloride
Injection USP

REF Q8020
NDC 0264-5804-00

1000 mL
EXCEL® PLUS CONTAINER

Each 100 mL contains: Sodium Chloride USP 0.45 g;
Water for Injection USP qs

pH adjusted with HCl NF
pH: 5.6 (4.5-7.0); Calc. Osmolarity: 154 mOsmol/liter, hypotonic

Electrolytes (mEq/liter): Na^+ 77; Cl^- 77

Sterile, nonpyrogenic. Single-dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Store at 20 to 25°C (68 to 77°F); excursions permitted 15 to 30°C (59 to 86°F). [See USP Controlled Room Temperature.]

Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

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B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862

Y94-003-360
LD-632-1

EXP
LOT

0.45% Sodium Chloride Injection USP

REF Q8020
NDC 0264-5804-00

1000 mL
EXCEL® PLUS CONTAINER

-0-

-1-

Each 100 mL contains: Sodium Chloride USP 0.45 g; Water for Injection USP qs

-2-

pH adjusted with HCl NF
pH: 5.6 (4.5–7.0); Calc. Osmolarity: 154 mOsmol/liter, hypotonic

Electrolytes (mEq/liter): Na^+ 77; Cl^- 77

-3-

Sterile, nonpyrogenic. Single-dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

2D CODE

-4-

WARNINGS: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

-5-

Store at 20 to 25°C (68 to 77°F); excursions permitted 15 to 30°C (59 to 86°F). [See USP Controlled Room Temperature.]

Avoid excessive heat. Protect from freezing. See Package Insert.

-6-

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

-7-

Not made with natural rubber latex, PVC or DEHP.

EXCEL is a registered trademark of B. Braun Medical Inc.

Rx only

7 OTHER

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0264-5802
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	0.9 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0264-5802-00	12 in 1 CASE	01/26/2022	
1		1000 mL in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:0264-5802-10	24 in 1 CASE	01/26/2022	
2		500 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019635	03/09/1998	

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0264-5804
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	0.45 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0264-5804-00	12 in 1 CASE	01/26/2022	
1		1000 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019635	03/09/1988	

Labeler - B. Braun Medical Inc. (002397347)

Revised: 1/2022 B. Braun Medical Inc.