B. BRAUN MEDICAL INC.
861 Marcon Blvd.
Allentown, PA 18109
Telephone: (833) 425-1464
Fax: (610) 849-1197
E-mail: ProductQualityExcellence@bbraunusa.com

09 March 2023

IMPORTANT DRUG WARNING

Subject: Potential Leakage and Clarification of External Pressure Application to 0.9% Sodium Chloride Injection USP and 0.45% Sodium Chloride Injection USP in EXCEL® Plus Containers for Intravenous Administration

Dear Healthcare Provider:

The purpose of this letter is to inform you of important information concerning potential leakage with the application of external pressure to the following products:

Product Code	NDC	Description
Q8000	0264-5802-00	0.9% Sodium Chloride Injection USP in EXCEL® Plus Container, 1000 mL
Q8001	0264-5802-10	0.9% Sodium Chloride Injection USP in EXCEL® Plus Container, 500 mL
Q8020	0264-5804-00	0.45% Sodium Chloride Injection USP in EXCEL® Plus Container, 1000 mL

B. Braun has received reports of occurrences of **ejection of the medication port stopper and product leakage when the container has been pressurized after accessing the medication port**. Specifically, these instances have occurred most frequently when the containers have been pressurized utilizing a pressure cuff, but some instances have also been identified after stacking accessed containers during storage and handling activities. Therefore, it is important to clarify the current capabilities of the product.

The labeling for the product indicates:

> 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.

B. Braun has test data on file to support the following:

- Containers where the medication port has not been accessed can be pressurized with pressure cuffs at pressures up to and including 300 mmHg for up to 24hrs when utilizing the pressure cuffs listed in Appendix 1 of this notice.
- The medication port functions as intended and reseals when accessed with an 18 to 22 gauge needle and is pressurized at 150 mmHg for 24 hours.
- During storage, EXCEL® Plus Containers may be stacked up to five (5) units high prior to accessing the medication port. Do NOT stack the EXCEL® Plus Containers after accessing the medication port.

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Risks Associated with Use of the Impacted Product

- Exposing the product to conditions outside those identified herein may result in leakage. If the container is being pressurized to maintain an arterial line and leakage occurs, there may be blood loss as well as a loss of pressure monitoring ability. If leaking occurs during an infusion that is pressurized for rapid infusion due to clinical need, the patient's treatment may be delayed since their initial resuscitation may be inadequate. Depending on the extent and duration of leak the severity of these events may range from mild and transient to life-threating. In addition, if a leak occurs, there is a risk the fluid in the container could become contaminated, which could cause an infection in the patient. **Leaking containers pose a risk to sterility of the contents and should not be used.**

Actions for Users:

- Inform all clinicians in your facility of the information in this notification.
- Be aware that external pressure (e.g., stacking, use of a pressure bag,) on EXCEL® Plus Containers can cause leaking in certain situations.
- If leakage is observed, do not use the particular product container and discard the product.
- **Storage**
  - DO NOT stack the containers more than five (5) units high prior to accessing the medication port
  - DO NOT stack the containers at all after accessing the medication port.
- **Pressured Infusions**
  - DO NOT apply excessive pressure greater than 300mmHg to the EXCEL® Plus Containers at any time with pressure cuffs or twist the bags when applying pressure as noted in the product labeling.
  - Using the medication port:
    - If infusions using external pressure are required for patient care, **if possible, do not use the medication port** on the EXCEL® Plus Containers to add medication prior to use. Find an alternative method to administer the medication to the patient.
    - **If the medication port must be accessed prior to a pressured infusion**, do not apply pressure exceeding 150 mmHg for 24 hours. DO NOT exceed this pressure on containers where the medication port has been accessed with a 18 to 22 gauge needle.
  - NOT using the medication port:
    - If an external pressure bag is required for patient care, **only use the pressure bags listed in Appendix 1** of this notice up to 300mmHg. Other pressure bags were not tested by B. Braun and may be at risk of causing leakage to the in EXCEL® Plus Container.

  - Based on the above information, evaluate the rapid infusers at your facility to determine if the EXCEL Plus IV containers can continue to be used in those devices. Contact B.Braun at 1-800-854-6851 or email medinfo.us@bbraunusa.com to discuss this further, if needed.

- B. Braun will provide a laminated sign with this information to post where the EXCEL® Plus Containers are stored to ensure these instructions are followed. Until you receive this sign, please post this notification in that location.

Actions for Distributors

If you are a distributor, please ensure a copy of this notice is forwarded to your consignees. Please refer any inquiries to our Medical Affairs department by calling 1-800-854-6851 or email to medinfo.us@bbraunusa.com.

Actions Being Taken by B. Braun

B. Braun will provide a laminated sign to customers to hang in the location where the EXCEL Plus IV containers are stored. To obtain additional signs, please contact your local B. Braun sales representative.

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B. Braun is working to further enhance the product design and manufacturing processes to accommodate a broader range of pressures and durations after access of the medication port.

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events in patients administered Sodium Chloride for Injection USP to B. Braun at 1-833-425-1464.

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 Sodium Chloride for Injection USP.

This letter is not intended as a complete description of the benefits and risks related to the use of Sodium Chloride for Injection USP. Please refer to the enclosed full prescribing information.

Sincerely,

Electronically signed by: Jonathan Severino
Reason: For the reason(s) specified in the document.
Date: Mar 9, 2023 18:14 EST

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

Enclosure(s)
Sodium Chloride Injections USP Full Prescribing Information

B. BRAUN MEDICAL INC.
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Appendix 1
List of Pressure Cuffs Tested with EXCEL® Plus IV Container

- BD Carefusion Vital Signs IN900012
- Mason Tayler Infu-Stat MTM305
- Mason Tayler Infu-Stat MTM310
- Medex MX4705
- Medex MX4810
- Medical Unifusor 1104X-5
- Moog/Ethox Infu-Surg 4010
- PremierPro Pressure Infuser 8801
- Unifusor 903SGA
- Unifusor 904SGA

For information concerning compatibility of the EXCEL Plus Container with pressure cuffs not identified herein, please contact B. Braun's Medical Affairs department by calling 1-800-854-6851 or email medinfo.us@bbraunusa.com.

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		

NDC	REF	Size
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

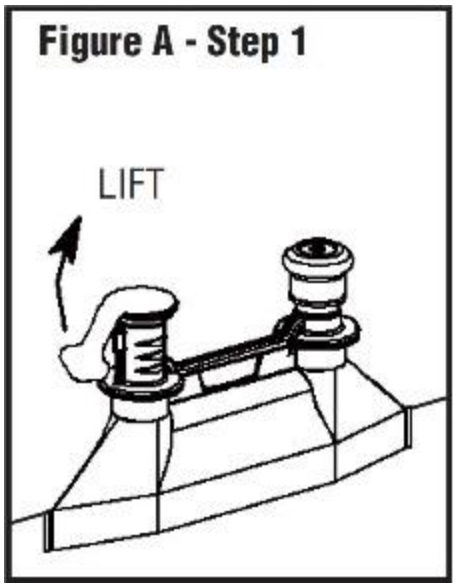
Tear overwrap down at notch and remove solution container. Check for minute leaks by squeezing solution container firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below before preparing for administration.

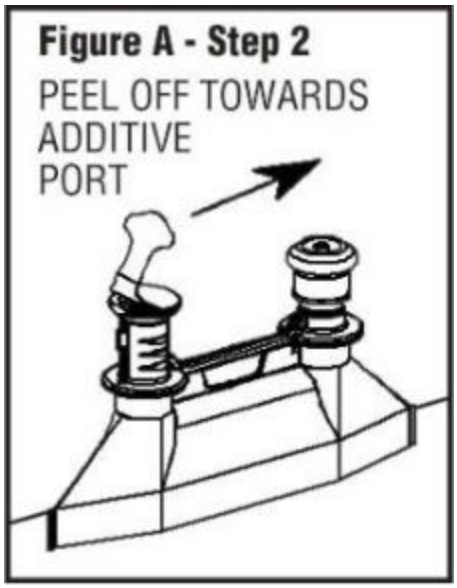
NOTE: Before use, perform the following checks:

- 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

-2-

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

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

-8-

PRINCIPAL DISPLAY PANEL - 0.9 g/500 mL Container Label

0.9% Sodium Chloride
Injection USP

REF Q8001
NDC 0264-5802-10

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

Y94-003-357
LD-630-1

500 mL
EXCEL® PLUS CONTAINER

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

BARCODE

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

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

BARCODE

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.

EXP LOT

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

7
OTHER

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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.

-2-

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

7 OTHER

-3-

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B|BRAUN

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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

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

Y94-003-360
LD-662-1

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0264-5802
Route of Administration	INTRAVENOUS		

BARCODE

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

BARCODE

EXP LOT

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.