**Sodium Chloride Injection USP 0.9%**

**PRESCRIBING INFORMATION**

Rx only

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### DOSAGE AND ADMINISTRATION

1. **For use in flushing compatible contrast agents through Mallinckrodt intravenous administration sets into indwelling intravenous access devices**

2. **For single patient use only**

   - Determine the volume of flush based on the imaging procedure, location of the vascular access device, length of tubing between power injector and vascular access device, and the contract agent package insert.

   - Individualize the volume of the flush based on body weight, fluid status and concomitant medical conditions.

   - Typical flush volumes for adults are 10 to 25 mL per injection at rates not to exceed 10 mL/sec.

   - May be used for additional infusion to maintain the patency of vascular access at a typical infusion rate of 0.5 to 1 mL per minute.

   - Do not use if packaging is damaged, wet, or not intact, if syringe or its tip cap shows signs of damage, leakage or displacement. Do not use if solution is hazy, cloudy, discolored, or contains particulate matter.

   - Use aseptic technique.

   - Expel residual air from the syringe and tubing prior to connection with the patient’s vascular access.

3. **Supplied as a clear, colorless, odorless, sterile solution of Sodium Chloride 0.9% for intravenous administration**

4. **Adverse reactions due to solution or administration technique may include**: air embolism with stroke, chest pain, and dyspnea, arrhythmias, hypotension, myocardial infarction, sepsis, febrile response, local tenderness, infection at the site of injection, venous thrombosis or phlebitis extending from injection site, extravasation, fluid overload and hypervolemia.

   - To report SUSPECTED ADVERSE REACTIONS, contact Mallinckrodt LLC at 1-855-266-5037 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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### CONTRAINDICATIONS

- None

### WARNINGS AND PRECAUTIONS

- Remove all air from the syringe and associated tubing prior to injection.

- May cause fluid overload in patients with congestive heart failure, severe renal insufficiency, and in clinical states with edema, sodium retention, or hypernatremia.

- Establish intravascular catheter patency prior to administration.

### ADVERSE REACTIONS

- Adverse reactions due to solution or administration technique may include:

- Pregnancy: It is not known whether Sodium Chloride Injection USP 0.9% can cause fetal harm. (8.1)

- Pediatric Use: Safety and effectiveness have not been established in pediatric patients. (8.4)

- Geriatric Use: Dosing for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. (8.5)

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### DOSAGE FORMS AND STRENGTHS

- Supplied in 50 mL and 125 mL prefilled syringes

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**2.3 125 mL Syringe Assembly and Inspection**

NOTE: Exterior of syringe is not sterile. Contents of syringe and area under tip cap and piston ribs are sterile and should be treated accordingly.

Remove syringe from carton and inspect the area around the tip cap and outside of piston for signs of leakage. Do not use if leakage is observed. Load syringe into power injector.

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**2.2 50 mL Syringe Assembly and Inspection**

NOTE: Exterior of syringe is not sterile. Contents of syringe and area under tip cap and piston ribs are sterile and should be treated accordingly.

Remove syringe from carton and inspect the area around the tip cap and outside of piston for signs of leakage. Do not use if leakage is observed.
Reported adverse reactions include:
- febrile response
- local tenderness
- infection at the site of injection
- venous thrombosis or phlebitis extending from injection site
- extravasation
- fluid overload
- hyperkalemia

8.5 Geriatric Use

No clinical studies of Sodium Chloride Injection USP 0.9% were conducted. Other reported clinical experience with sodium chloride injection has not identified differences in responses between the 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.

10 OVERDOSAGE

Use of Sodium Chloride Injection USP 0.9% may pose a threat of overdose marked by electrolyte disturbance and/or fluid overload, particularly in pediatric patients and patients with compromised renal or cardiac function. In the event of overdose, discontinue the infusion, reevaluate the patient and institute appropriate corrective action.

11 DESCRIPTION

Sodium Chloride Injection USP 0.9% is a formulation of sodium chloride in water for Intravenous Injection. No preservative, antimicrobial agent or buffer is added. Sodium Chloride Injection USP 0.9% is provided as a sterile, nonpyrogenic, clear, colorless, odorless solution.

Molecular formula = NaCl

MW = 58.44

Each ml of Sodium Chloride Injection USP 0.9% contains 9 mg of sodium chloride. The pH is 4.5 to 7.0. The osmolality is 308 mOsm/L (ca. L)

12 CLINICAL PHARMACOLOGY

Sodium Chloride Injection USP 0.9% has an osmotic pressure similar to plasma.

16 HOW SUPPLIED/STORAGE AND HANDLING

Sodium Chloride Injection USP 0.9% is a clear, colorless, odorless solution containing 9 mg/ml of sodium chloride. Sodium Chloride Injection USP 0.9% is supplied in 50 and 125 mL prefilled syringes containing 50 and 125 mL of solution respectively.

Each syringe is sealed with rubber closures and the contents are sterile. The 125 mL syringe is supplied with a luer locknut adapter which is cleared for manufacture and distribution as a device under 510(k) 86265). The syringes are contained in shipping cartons with the following configurations:

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<td>125 mL</td>
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<tr>
<td>125 mL</td>
<td>in plastic RFID-Tagged Syringes*</td>
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*Radio Frequency Identification (RFID) Technology

RFID-Tagged Syringe Description

This information is for Ultraject™ syringes containing Sodium Chloride Injection USP 0.9% that has been labeled with a Radio Frequency Identification (RFID) tag. When used with an RFID-enabled Optivantage Injector, this tag allows for the exchange of product information such as lot number, expiration, concentration, and identification of the syringe as being unused prior to use and used after product administration. Patient information is not utilized in any form with this RFID technology. Sodium Chloride Injection USP 0.9% product quality is not impacted with the use of this RFID tag. Sodium Chloride Injection USP 0.9% RFID syringes require no special handling and should be stored at the conditions listed for the drug product.

RFID-Tagged Syringes Directions for Use

For the RFID technology to function, the syringe must be used with an Optivantage Injector with RFID technology. Function of the RFID technology is not dependent on syringe orientation as it is placed in the injector. Instructions for use of the injector are provided on the injector interface screens and operator’s manual.

Regarding interference with medical devices, the RFID tag and injector system meet the IEC 60601-1-2 requirements for emission and immunity standards for medical devices. Follow all manufacturers’ guidelines and do not operate any part of the Optivantage Injector System and RFID-tagged syringes within 6 inches (15 cm) of a pacemaker and/or defibrillator.

Storage

Store Sodium Chloride Injection USP 0.9% syringes and RFID-tagged syringes at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) (see USP Controlled Room Temperature).

PROTECT FROM FREEZING

Manufactured by:

Lieser-Flanzech Company LLC

Raleigh, NC 27616

Made in USA

GBT 11880916

Issued: 09/16
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