

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use the SODIUM CHLORIDE INJECTION, USP, 0.9% safely and effectively. See full prescribing information for SODIUM CHLORIDE INJECTION, USP, 0.9%.

SODIUM CHLORIDE INJECTION, USP, 0.9%

Initial U.S. Approval: 2012

INDICATIONS AND USAGE

Sodium Chloride Injection, USP, 0.9% is indicated for:

- Dilution or Dissolving the drugs for intravenous, intramuscular or subcutaneous injections (1.1).

DOSAGE AND ADMINISTRATION

- Volume of preparation to be used for diluting or dissolving any drug for injection is dependent on the vehicle concentration, dose and route of administration recommended by the drug manufacturer (2.1).

DOSAGE FORM AND STRENGTHS

- Injection, 0.9%

CONTRAINDICATIONS

- None

WARNING AND PRECAUTIONS

- Consult the drug product manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving drugs to be injected including the route and rate of injection (5.1).
- Do not use Sodium Chloride Injection, USP, 0.9% if the solution is discolored, cloudy, hazy, or contains a precipitate, or if the syringe is damaged (5.1).
- For single use only. Discard unused portion (5.2).

ADVERSE REACTIONS

- Reactions that may occur because of this solution, added drugs or the technique of reconstitution or administration include air embolization, febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasations (6).
- To report SUSPECTED ADVERSE REACTIONS, contact MEDEFIL, INC. at tel: 1-630-682-4600 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

DRUG INTERACTION

- Some drugs or injections may be incompatible when combined with 0.9% sodium chloride.
- Consult with a pharmacist, if unsure of compatibility (7).

See 17 for PATIENT COUNSELING INFORMATION.

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Medefil, Inc.

"Sodium Chloride Injection, USP 0.9%"

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*Sections or subsections omitted from the full prescribing information are not listed.

1 INDICATIONS AND USAGE

1.1 Dilution or Dissolution of Drugs

Sodium Chloride Injection, USP, 0.9% is indicated for diluting or dissolving drugs for intravenous, intramuscular or subcutaneous injection, according to instructions of the manufacturer of the drug to be administered.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

- The volume of preparation to be used for diluting or dissolving any drug for injection is dependent on the vehicle concentration, dose and route of administration as recommended by the drug manufacturer.

2.2 Instruction for Administration (Refer figure 1 – figure 5 for pictorial presentation on back of this page)

- Solution and fluid path are sterile and non-pyrogenic if the tip cap is in place, syringe is intact and there is no evidence of leakage. Use proper aseptic technique.
- Inspect plastic wrapping. Do not use if plastic wrapping is damaged or not intact. (Figure 1)
- Remove plastic packaging by tearing along perforation. (Figure 2)
- Do not use if, solution is discolored, cloudy, hazy, or contains a precipitate, or if the syringe is damaged. (Figure 3)
- With the tip cap of the syringe on, press the syringe forward to properly activate the syringe. Improper activation may difficult syringe use and/or may cause plunger rod separation. **Never draw back rod because the product may become contaminated.** (Figure 4)
- Remove tip cap. Hold the syringe unit upright and prime to expel any air bubble if present. (Figure 5)
- Syringe is now ready to use.
- Use aseptic techniques for diluting or dissolving drugs, mix thoroughly and use according to the drug manufacturer's label instructions.
- Discard empty unit after use. Discard any unused portion. Do not reuse disposable syringes.

2.3 Preparation and Handling Precautions

- Before use check for any possible incompatibility with sodium chloride.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

- Do not store reconstituted solution or drugs for injection unless otherwise directed by the manufacturer of the solute.
- Adding additives may be incompatible.
- Do not use if, solution is discolored, cloudy, hazy, or contains a precipitate, or if the syringe is damaged.
- Do not freeze.
- Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat.

3 DOSAGE FORMS AND STRENGTHS

10 mL fill in 12 mL syringe, 0.9% Sodium Chloride, USP, single use.

4 CONTRAINDICATIONS

None

5 WARNINGS AND PRECAUTIONS

5.1 General

When used to dilute drug products, consult the drug product manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving drugs to be injected including the route and rate of injection. Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration. Do not use Sodium Chloride Injection, USP 0.9% if the solution is discolored, cloudy, hazy, or contains a precipitate, or if the syringe is damaged.

5.2 For Single Use Only

Re-use of single-use product creates a potential risk to the user. Contamination of product and/or limited functionality of the syringe may lead to injury, illness or death. Discard any unused portion.

6 ADVERSE REACTIONS

Adverse reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include, but are not limited to, air embolization, febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and if possible, retrieve and save the remainder of unused vehicle for examination if deemed necessary.

7 DRUG INTERACTIONS

Some drugs or injections may be incompatible when combined with 0.9% sodium chloride. Before Sodium Chloride Injection, USP, 0.9% is used as a vehicle for the administration of a drug, the drug product manufacturer's instructions or other specific references should be checked for any possible incompatibility with sodium chloride. Consult with a pharmacist, if unsure of compatibility.

11 DESCRIPTION

Sodium Chloride Injection, USP 0.9% is a sterile, nonpyrogenic, isotonic solution of sodium chloride and water for injection. It contains no bacteriostatic antimicrobial agents or added buffer. The nominal pH is 5.5 (4.5 to 7.0). Hydrochloric acid and/or sodium hydroxide may have been added for pH adjustment. Sodium Chloride Injection, USP, 0.9% contains 9 g/L Sodium Chloride, USP (NaCl) with a calculated osmolarity of approximately 308 mOsmol/L. It contains 154 mEq/L sodium and 154 mEq/L chloride. The syringe component of Sodium Chloride Injection, USP, 0.9% is manufactured with polypropylene and luer lock. The syringe is not made with natural rubber latex. The syringe is not made with DEHP. This product contains no preservative. The syringes require no vapor barrier to maintain the proper drug concentration. The empirical formula for sodium chloride is NaCl and the molecular weight is 58.44 g/mol. Supplied as single use syringes.

12 CLINICAL PHARMACOLOGY

Sodium chloride in water dissociates to provide sodium (Na⁺) and chloride (Cl⁻) ions. These ions are normal constituents of the body fluids (principally extracellular) and are essential for maintaining electrolyte balance. The small volume of fluid and amount of sodium chloride provided by Sodium Chloride Injection, USP, 0.9% when used only as an isotonic vehicle for parenteral injection of drugs or for flushing of indwelling access devices, is unlikely to exert a significant effect on fluid and electrolyte balance except possibly in neonates and very small infants.

16 HOW SUPPLIED/STORAGE AND HANDLING

The drug product is packaged in a clear plastic hypodermic syringe, which consists of a hypodermic barrel with luer lock, plunger stopper, plunger rod, and tip cap. There are two syringe sizes (6 mL and 12 mL), intended for single use and subsequent disposal. Medefil is approved for the following fill volumes

- 6 mL syringe: 1 mL, 2 mL, 2.5 mL, 3 mL, and 5 mL.
- 12 mL syringe: 3 mL, 5 mL, and 10 mL.

Currently, the drug product is marketed only as 10mL fill in 12mL syringe. The filled 6 mL and 12 mL syringes are packaged individually in plastic pouches.

DOSAGE FORM

Product Number	NDC	Fill Volume
MSD-0230	64253-202-30	10 ml fill in 12 ml syringe

The above products are available in boxes of 30, 60 or 120 count each.

STORAGE AND HANDLING

Store at 25°C (77°F); excursions permitted to 15°-30°C (59° - 86°F). Do not freeze.

17 PATIENT COUNSELING INFORMATION

17.1 When using to dilute drug products, consult the drug product manufacturer's instruction to confirm compatibility, appropriate dilution or volume for dissolving drugs including the route and rate of injection. Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration. Do not use Sodium Chloride Injection, USP 0.9% if the solution is discolored, cloudy, hazy, or contains a precipitate, or if the syringe damaged [see *Warning and Precautions, section 5.1*].

17.2 Syringes are for single use only. Discard unused portions and dispose of the unit in an appropriate sharps container. [see *Warning and Precautions, section 5.2*].

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**0.9% Sodium Chloride Injection, USP
(Normal Saline I. V. Flush Syringe)**

DESCRIPTION

Normal Saline I. V. Flush Syringe is available in different volumes. It is sterile, non-pyrogenic aqueous isotonic solution of Sodium Chloride. Each mL contains 9 mg/mL sodium chloride. The total osmolar concentration of solution is 0.31 mOsm/ml (calc.). The pH of the solution is 4.5 – 7.0. The syringe component of 0.9% Sodium Chloride Injection, USP is manufactured with polypropylene and luer lock. The syringe is not made with natural rubber latex. The syringe is not made with DEHP. The product contains no preservative.

CLINICAL PHARMACOLOGY

Normal Saline I. V. Flush Syringe is a sterile aqueous solution having approximately the same osmotic pressure and composition as the extracellular fluid. It is non-irritating to the tissues.

INDICATIONS AND USAGE

For use as a sterile isotonic injection for flushing compatible intravenous tubing and/or indwelling access devices only.

PRECAUTIONS

Caution must be exercised to avoid any contact between Normal Saline flush solution and incompatible drugs. Consult appropriate literature for compatibility data before flushing the catheter containing drug product with Normal Saline I. V. Flush Syringe. Do not administer if a precipitate appears, or if the solution is discolored, or hazy, or if the syringe is damaged. For single use only. Discard unused portion.

ADVERSE REACTIONS

None known from use in these quantities.

DRUG ABUSE AND DEPENDENCE

Not Applicable.

OVERDOSAGE

None known from use in these quantities.

DOSAGE AND ADMINISTRATION

Lock flush solution is injected as a single dose via the injection side of vascular access device. The volume injected is equivalent to that of the vascular access device. After each time the vascular access device has been used for the injection or infusion of the medication, the Lock Flush solution should be injected to restore the patency of the vascular access device. Aspirate before administering any solution via the access device lock in order to confirm patency and location of the catheter tip.

STORAGE

Store at 25°C (77°F), excursions permitted to 15°-30°C (59°-86°F). Do not freeze.

WARNING

Re-use of single-use devices create a potential risk to patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

DIRECTIONS FOR USE (Refer figure 1 – figure 9 for pictorial presentation)

1. Solution and fluid path are sterile and non-pyrogenic if the tip cap is in place, syringe is intact and there is no evidence of leakage. Use proper aseptic technique.
2. Inspect plastic wrapping. Do not use if plastic wrapping is damaged or not intact. (Figure 1)
3. Remove plastic packaging by tearing along perforation. (Figure 2)
4. Do not use if, solution is discolored, cloudy, hazy, or contains a precipitate, or if the syringe is damaged. (Figure 3)
5. With the tip cap of the syringe on, press the syringe forward to properly activate the syringe. Improper activation may difficult syringe use and/or may cause plunger rod separation. **Never draw back rod because the product may become contaminated.** (Figure 4)
6. Remove tip cap. Hold the syringe unit upright and prime to expel any air bubble if present. (Figure 5)
7. Syringe is now ready to use. Per Institution protocol attach flush syringe to access device and flush. (Figure 6)
8. When attempting to aspirate tubing or indwelling device by pulling back on the syringe plunger, while attached to the tubing or indwelling device, use two-handed technique with one hand on the syringe barrel and the other on the plunger. Pull the plunger straight back. Do not pull or bend the plunger sideways. (Figure 7)
9. Use in accordance with intravenous tubing or indwelling device manufacturer's recommendation. (Figure 8)
10. Discard empty unit after use. Discard any unused portion. Do not reuse disposable syringes. (Figure 9)

HOW SUPPLIED

0.9% Sodium Chloride Injection, USP is available as follows:

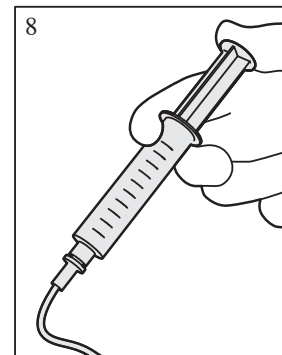
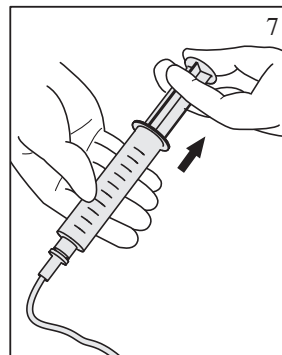
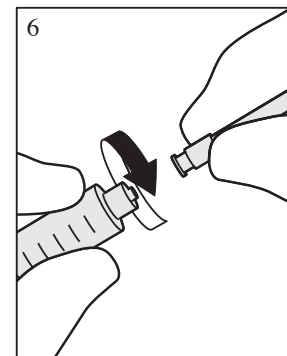
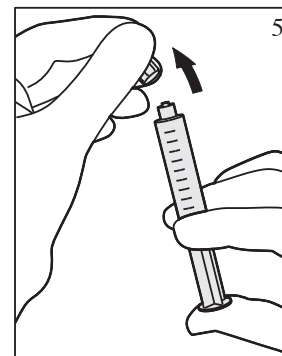
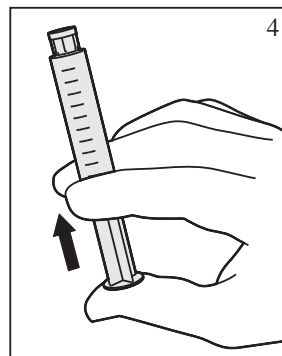
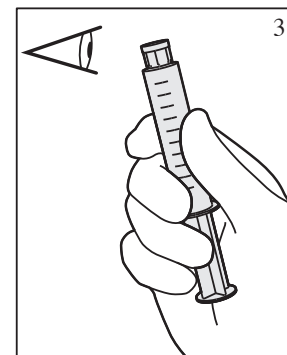
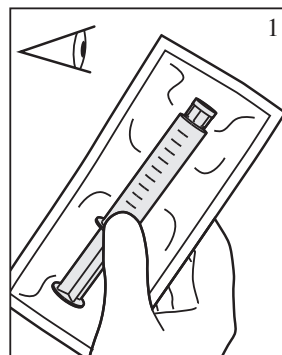
- 1 mL fill in 6 mL Syringe
- 2 mL fill in 6 mL Syringe
- 2.5 mL fill in 6 mL Syringe
- 3 mL fill in 6 mL Syringe
- 5 mL fill in 6 mL Syringe
- 3 mL fill in 12 mL Syringe
- 5 mL fill in 12 mL Syringe
- 10 mL fill in 12 mL Syringe

The above products are available in boxes of 30, 60 or 120 count each

CAUTION

Federal (USA) law restricts the device to sale by or on order of a physician. **DO NOT PLACE THE DEVICE ON A STERILE FIELD.**

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Note: For detailed handling information see instruction for use.