**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%**

**----------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).

**----------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).

**-------DOSAGE FORM AND STRENGTHS------**
Injection, 0.9%

**----------ADVERSE REACTIONS----------**

- Reactions that 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 extravasations (6).

**See 17 for PATIENT COUNSELING INFORMATION.**

**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.**

Revised: 09/2012

**Medefil, Inc.**

**"Sodium Chloride Injection, USP 0.9%"**

**FULL PRESCRIBING INFORMATION: CONTENTS***

## 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 Dilution or Dissolution of Drugs

- 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.
- Use aseptic techniques for diluting or dissolving drugs, mix thoroughly and use according to the drug manufacturer's label instructions.
- Do not store reconstituted solution or drugs for injection unless otherwise indicated in the drug manufacturer's labeled instructions.
- Discard the syringe including any unused portion after use.

## 3 DOSAGE AND STRENGTHS

1 mL, 2 mL, 2.5 mL, 3 mL and 5 mL fill in 6 mL syringe, single use
3 mL, 5 mL and 10 mL fill in 12 mL syringe, 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 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 device 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 luer lock. The device has no components made of natural rubber latex. 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.

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. The fill volumes for the 6 mL syringe are 1 mL, 2 mL, 2.5 mL, 3 mL, and 5 mL. The fill volumes for the 12 mL syringe are 3 mL, 5 mL, and 10 mL. The filled 6 mL and 12 mL syringes are packaged individually in plastic pouches and 60 syringes are packaged into each dispensing box.

DOSAGE FORM

| Product Number | NDC | Fill Volume |
|---|---|---|
| MSD-0221 | 64253-202-21 | 1 ml fill in 6 ml syringe |
| MSD-0222 | 64253-202-22 | 2 ml fill in 6 ml syringe |
| MSD-0252 | 64253-202-52 | 2.5 ml fill in 6 ml syringe |
| MSD-0223 | 64253-202-23 | 3 ml fill in 6 ml syringe |
| MSD-0233 | 64253-202-33 | 3 ml fill in 12 ml syringe |
| MSD-0225 | 64253-202-25 | 5 ml fill in 6 ml syringe |
| MSD-0235 | 64253-202-35 | 5 ml fill in 12 ml syringe |
| 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 PATIENT HANDLING INFORMATION

17.1 When using to dilute drug products, consult the drug product manufacturer's instructions 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 USP 0.9% if the solution is discolored, cloudy, hazy, or contains a precipitate, or if the syringe is damaged *[see Warnings 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 Warnings and Precautions, section 5.2]*.

Medefil, Inc., 250 Windy Point Drive, Glendale Heights, IL 60139. **Prepared XX/2012**