A3419-20 SINGLE SHOT EPIDURAL 20G TUOHY -
Smiths Medical ASD, Inc.

Spectra Medical Devices, Inc.
SODIUM CHLORIDE
INJECTION, USP, 0.9%
DESCRIPTION
Sodium Chloride Injection, USP is a sterile, nonpyrogenic, isotonic solution of sodium chloride 0.9% (9mg/mL) in Water for Injection containing no antimicrobial agent or other added substance. The pH is between 4.5 and 7.0. Its chloride and sodium ion concentrates are approximately 0.154 mEq of each per milliliter and its calculated osmolality is 0.308 milliosmols per mL.
Sodium chloride occurs as colorless cubic crystals or white crystalline powder and has a saline taste. Sodium Chloride is freely soluble in water. It is soluble in glycerin and slightly soluble in alcohol. The empirical formula for sodium chloride is NaCl, and the molecular weight is 58.44.
CLINICAL PHARMACOLOGY
Sodium chloride comprises over 90% of the inorganic constituents of the blood serum. Sodium chloride in water dissociates to provide sodium (Na+) and (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 a vehicle for parenteral injection of drugs, is unlikely to exert a significant effect on fluid and electrolyte balance except possibly in very small infants.
INDICATIONS AND USAGE
Sodium Chloride Injection is used to flush intravascular catheters or as a sterile, isontonic single dose vehicle, solvent, or diluent for substances to administered intravenously,k intramuscularly or sub-cutaneously and for other extemporaneously prepared single dose sterile solutions according to instructions of the manufacture of the drug to be administered.
WARNING
Sodium Chloride must be used with caution in the presence of congestive heart failure, circulatory insufficiency, kidney dysfunction or hypoproteinemia.
Excessive amounts of sodium chloride by any route may cause hypokalemia and acidosis. Excessive amounts by parental routes may precipitate congestive heart failure and acute pulmonary edema, especially seen in patients with preexisting cardiovascular disease and those receiving coricos-teroids, corticotrophin or other drugs that may give rise to sodium retention. For use in newborns, when a Sodium Chloride solution is required for preparation or diluting medications, or in flushing intravenous catheters, only preservative-free Sodium Chloride Injection, USP, 0.9% should be used.
PRECAUTIONS
GENERAL
Since Sodium Chloride Injection does not contain antimicrobial agents and is intended for single use, any unused amount must be discarded immediately following withdrawal of any portion of the contents of the vial or ampul. Do not open ampul until it is to be used.
Consult the manufactures instructions for choice of vehicle, appropriate dilution or volume for dissolving the drug to be injected, including the route and rate of injection.
PREGNANCY
CATEGORY C-Animal reproduction studies have not been conducted with Sodium Chloride Injection. It is also not known whether Sodium Chloride Injection can cause fetal harm when administered to a pregnant woman or can effect reproduction capacity. Sodium Chloride Injection should be given to a pregnant woman only if clearly needed.
ADVERSE REACTIONS
Reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include 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.
If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate countermeasures and if possible, retrieve and save the remainder of unused vehicle for examination.
OVERDOSAGE
When used as a diluent, solvent or intravascular flushing solution, this parental preparation is unlikely to pose a threat of sodium chloride or fluid overload except possible in very small infants. In the event these should occur, reevaluate the patient and institute appropriate corrective measures.
DOSAGE AND ADMINISTRATION
Before Sodium Chloride Injection, USP, 0.9% is used as a vehicle for the administration of a drug;specific references should be checked for any possible incompatibility with sodium chloride. The volume of the 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 manufacture.
Sodium Chloride Injection, USP, 0.9% is also indicated for use in flushing intravenous catheters. Prior to and after administration of the medication, the intravenous catheter should be flushed in its entirety with Sodium Chloride Injection, USP, 0.9%. Use in accord with any warnings or precautions appropriate to the medication being administered as recommended by the manufacture. **Parental**

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

HOW SUPPLIED

5 mL ampuls packaged in box of 50 each (NDC-65282-1505-1)
10 mL ampuls packaged in box of 50 each (NDC-65282-1510-1)
30 mL ampuls packaged in box of 30 each (NDC-65282-1530-3)

STORAGE

Store at controlled room temperature 15-30 C (59-86 F). Avoid freezing.

Manufactured for:
Spectra Medical Devices, Inc. 260-F Fordham Road, Wilmington, MA 01887
By: KM. Pharm Co., LTD.

Package Label Display Panel

REF **A3419-20**

SINGLE SHOT EPIDURAL

20G TUOHY

DRUGS:

1 Sodium Chloride (0.9%) 10ml

PROCEDURAL COMPONENTS:

1 Tuohy Epidural Needle Calibrated with Wings (20G x 3 ½ in. T.W.)
1 Glass L.O.R. Syringe (5ml, Metal Luer Lock)
1 25G x 1 ½ in. Needle
2 Plastic Syringes (10ml, Luer Lock)
1 Plastic Syringe (3ml, Luer Lock)
1 Plastic Syringe (3ml, Luer Lock) with 18G x 1 ½ in. Needle (Attached)
1 Filter Straw, 5µ
1 Medicine Cup, 50ml
1 Surgical Marker
1 Needle Stick Pad
1 Fenestrated Drape

PREP COMPONENTS:

1 Towel
4 Gauze Sponges

WARNING(S):

- A needle stick with a contaminated needle
- The use of excessive force while placing ne
  protrude through the bottom of the tray w

PRECAUTIONS:

- **Use Aseptic technique.**
- To help prevent needle-stick injuries, need
  excessive resistance is met during needle i
  occur. To help avoid needle breakage, do r
  and complete the procedure with a replace
- After use, place sharps in a suitable sharps co
  manner according to Centers for Disease Con
  regulations (EPA, OSHA) and health care fa
- Do NOT Resterilize.
- **NOTE:** See enclosure(s) for drug informati
  if solution is clear and colorless. Do not us
- To be used only by individuals familiar wi
  techniques and procedures, refer to stand

STORE AT CONTROLLE

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® indicates the trademark is registered in the
other countries.

Manufacturer:
Smiths Medical ASD, Inc.
Keene, NH 03431, USA
www.smiths-medical.com

Made in USA

LATEX

Caution • Do Not Reuse • Does n
if package is damaged • Steriliz
(U.S.A.) law restricts this device