A3408-18 PORTEX SINGLE SHOT EPIDURAL 18G HUSTEAD - regional anesthesia kit
Smiths Medical ASD, Inc.

3/4 Fluid Ounce Povidone Iodine

Povidone-iodine 10%

Antiseptic

Warnings

Do not use

- if allergic to iodine
- in the eyes

For external use only

Ask a doctor before use if injuries are

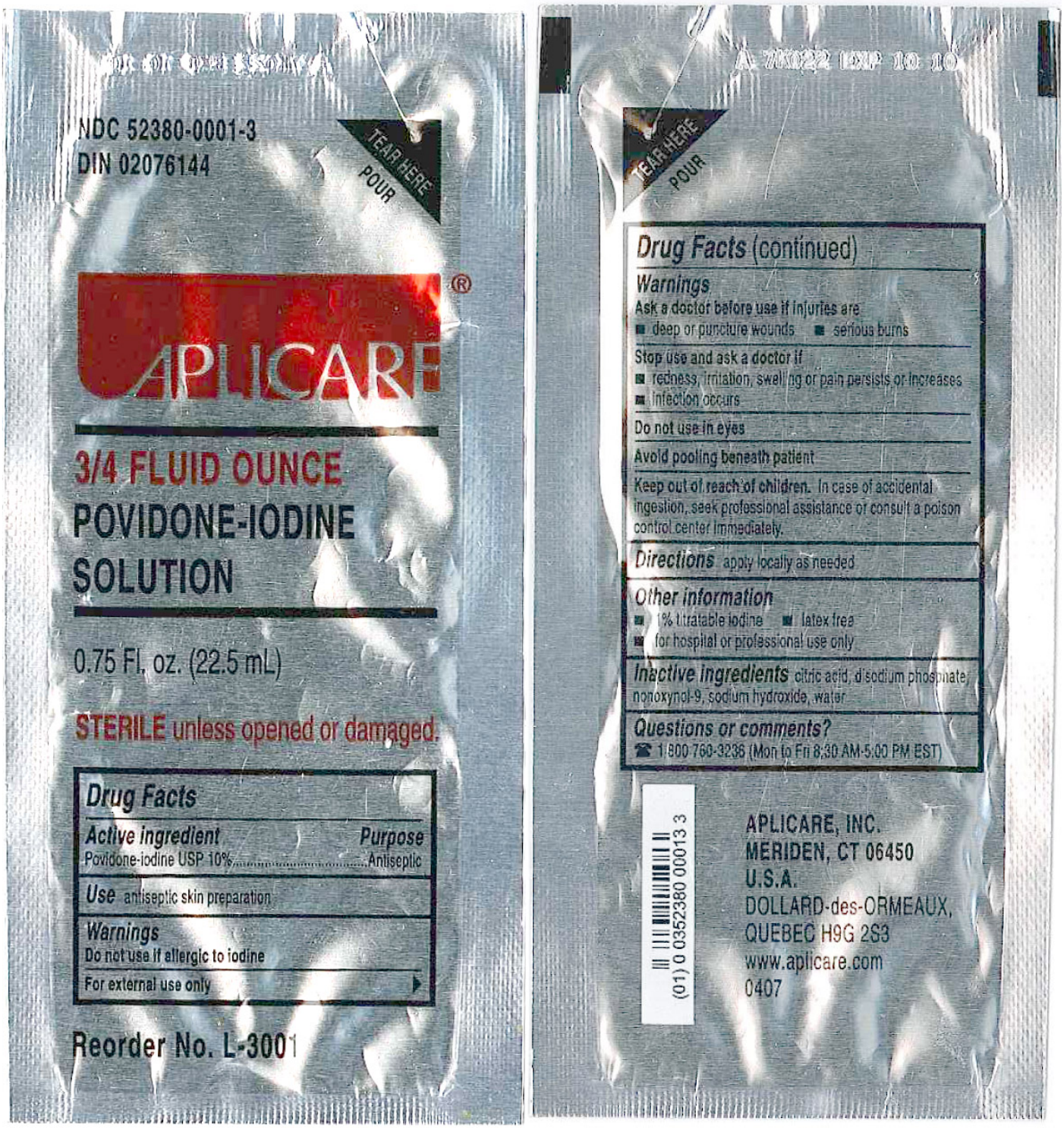
- deep or puncture wounds
- serious burns

Stop use and ask a doctor if

- redness, irritation, swelling or pain persists or increases
- infection occurs

Avoid pooling beneath patient

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.



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

PORTEX® SINGLE SHOT EPIDURAL
18G HUSTEAD

REF A3408-18

DRUGS:
1 Sodium Chloride (0.9%) 10ml
PROCEDURAL COMPONENTS:
1 Hustead Epidural Needle (18G x 3 ½ in. X.T.W.)
1 18G x 1 ½ in. Needle
1 22G x 1 ½ in. Needle
1 25G x 1 in. Needle
1 Glass L.O.R. Syringe (5ml , Metal Luer Slip)
1 Plastic Syringe (10ml, Luer Lock)
1 Plastic Syringe (3ml, Luer Lock)
1 Filter Straw, 5µ
1 Needle Stick Pad
1 Fenestrated Drape with 2 Tabs
PREP COMPONENTS:
1 Towel
4 Gauze Sponges
3 Sponge Applicators
1 Povidone-Iodine Solution, ¾ oz.

WARNINGS:
- As with all plastic wrapped products, do not open or unwrap in areas where static electric discharge may be hazardous, due to risk of explosion.
- A needle stick with a contaminated needle may cause infectious disease.
- The use of excessive force while placing needles into the stick pad may cause the needle to protrude through the bottom of the tray which may result in a contaminated needle stick.

PRECAUTIONS:
- **Use Aseptic technique.**
- To help prevent needle-stick injuries, needles should not be recapped or purposely bent. If excessive resistance is met during needle insertion, do not force the needle as damage may occur. To help avoid needle breakage, do not attempt to straighten a bent needle; discard it and complete the procedure with a replacement needle.
- After use, place sharps in a suitable sharps container. Dispose of contaminated product in a safe manner according to Centers for Disease Control and Prevention, USA and Federal/State/Local regulations (EPA, OSHA) and health care facility guidelines or local equivalent.
- Do NOT Resterilize.
- **NOTE:** See enclosure(s) for drug information. Confirm drug identity and integrity. Use only if solution is clear and colorless. Do not use if damaged.
- To be used only by individuals familiar with single shot epidural procedures. For specific techniques and procedures, refer to standard textbooks.

STORE AT CONTROLLED ROOM TEMPERATURE

smiths

Smiths Medical ASD, Inc.
Keene, NH 03431 USA
Made in USA
www.smiths-medical.com

LATEX Rx ONLY STERILE EO

Attention, see instructions for use. Do Not Reuse. Latex Free. Do not use if package is damaged. **Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Sterilized using ethylene oxide.

PLTA3408-18 REV. 000

(01) 0 03516880 69903

A3408-18 PORTEX SINGLE SHOT EPIDURAL 18G HUSTEAD

regional anesthesia kit kit

Product Information

Product Type	MEDICAL DEVICE	**Item Code (Source)**	NHRIC:51688-9387

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:51688-9387-2	10 in 1 CASE		
1		1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	22.5 mL
Part 2	1 AMPULE	10 mL

Part 1 of 2

APLICARE POVIDONE-IODINE

povidone-iodine solution

Product Information			
Item Code (Source)	NDC:52380-0001		
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE-IODINE (IODINE)	POVIDONE-IODINE	0.10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE	
SODIUM PHOSPHATE, DIBASIC	
SODIUM HYDROXIDE	
NONOXYNOL-9	
WATER	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:52380-0001-3	22.5 mL in 1 PACKET		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC monograph not final	part333A	03/01/1984	

Part 2 of 2

SODIUM CHLORIDE

sodium chloride solution

Product Information			
Item Code (Source)	NDC:65282-1510		
Route of Administration	EPIDURAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (SODIUM CATION)	SODIUM CHLORIDE	9 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65282-1510-1	10 mL in 1 AMPULE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/01/2000	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K965017	08/29/2006	

Labeler - Smiths Medical ASD, Inc. (137835299)

Establishment

Name	Address	ID/FEI	Business Operations
Smiths Medical ASD, Inc.		137835299	relabel, manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Aplicare, Inc.		107255002	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Kwang Myung Pharm. Co., Ltd.		631099384	manufacture

Revised: 10/2012 Smiths Medical ASD, Inc.