

**A3383-22 S.A.S. NERVE BLOCK 22G QUINCKE- anesthesia conduction kit  
Smiths Medical ASD, Inc.**

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**Drug Facts**

Povidone-iodine

Antiseptic

Antiseptic skin preparation

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

Avoid excessive heat. Store at room temperature.

Keep out of reach of children

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

Apply locally as needed.

- 1% titratable iodine
- latex free
- for hospital or professional use only

citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water

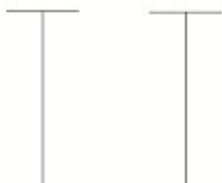
1 800 760-3236 (Mon to Fri 8:30 AM-5:00 PM EST)

APLICARE

POVIDONE-IODINE SOLUTION

ANTISEPTIC

STERILE Solution



NPN 02076144

POUR HERE



3/4 FLUID OUNCE  
POVIDONE-IODINE  
SOLUTION

0.75 Fl. oz. (22.5 mL)

STERILE unless opened or damaged.

Drug Facts

Active ingredient	Purpose
Povidone-iodine USP 10%	Antiseptic

Use antiseptic skin preparation

Warnings

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For external use only

Reorder No. L-3001

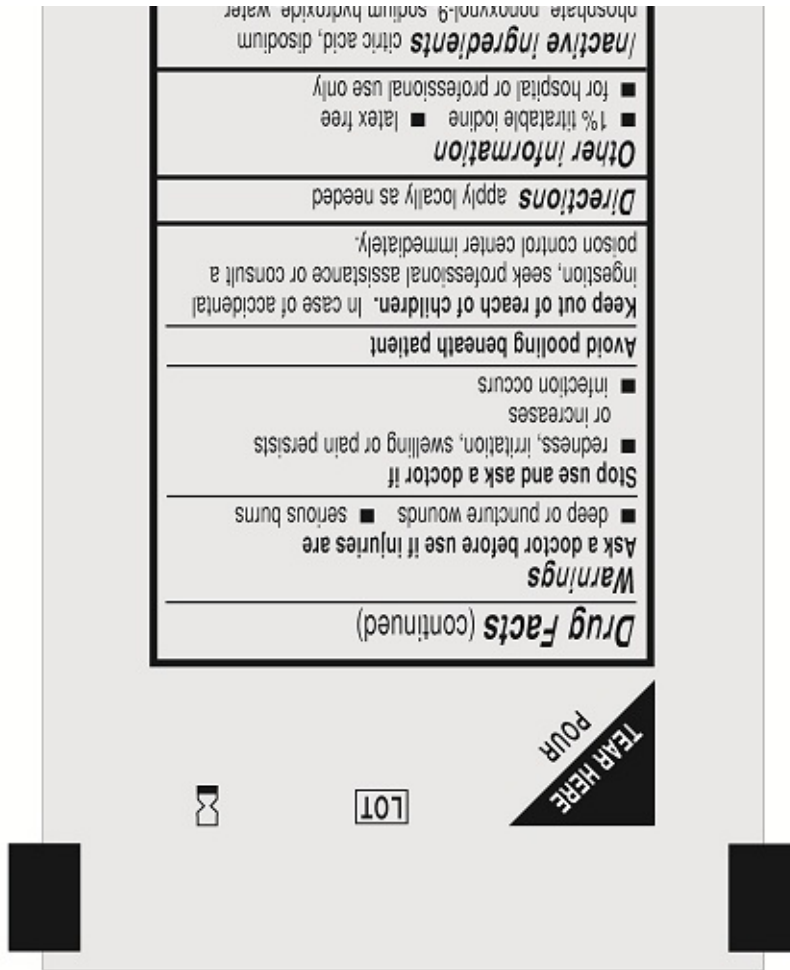
APLICARE, INC.  
MERIDEN, CT 06450  
U.S.A.  
DOLLARD-des-ORMEAUX,  
QUEBEC H9G 2S3  
www.aplicare.com  
0609



Questions or comments?  
1 800 760-3236 (Mon to Fri 8:30 AM-5:00 PM EST)

5.375"

10.75"



Package Label Display Panel

REF **A3383-22** **PORTEX**

**"S.A.S." NERVE BLOCK**  
22G QUINCKE

**PROCEDURAL COMPONENTS**

- Quincke Spinal Needle (22G x 3 1/2 in.)
- 18G x 1 1/2 in. Needle
- 27G x 1 1/2 in. T.W. Needle
- Plastic Syringe (12mL, Luer Lock)
- Plastic Syringe (3mL, Luer Lock)
- Needle Stick Pad
- Fenestrated Drape

**PREP COMPONENTS**

- Sponge Applicators
- Towel
- Gauze Sponges
- Povidone-Iodine Solution, 1/4 oz.

**WARNINGS:**

- 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 leakage, 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 (BPA, OSHA) and health care facility guidelines or local equivalent.
- Do NOT Reuse/sterilize.
- To be used only by individuals familiar with nerve block procedures. For specific techniques and procedures, refer to standard textbooks.

The Smiths Medical and Portex design marks are trademarks of Smiths Medical. The symbol ® indicates the trademark is registered in the U.S. Patent and Trademark Office and certain other countries.

Smiths Medical ASD, Inc.  
Kennebunk, ME 03431, USA  
www.smiths-medical.com  
Made in USA

PLTA3383-22 REV. 002 02/12

smiths medical

(01) 0 0351 688 06906 4

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## A3383-22 S.A.S. NERVE BLOCK 22G QUINCKE

anesthesia conduction kit kit

### Product Information

<b>Product Type</b>	MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:51688-9322
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:51688-9322-2	10 in 1 CASE		
1		1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product		

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	22.5 mL

Part 1 of 1

APPLICARE POVIDONE-IODINE

povidone-iodine solution

### Product Information

**Item Code (Source)** NDC:52380-0001

**Route of Administration** TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380-0001-3	22.5 mL in 1 PACKET; Type 0: Not a Combination Product		

### Marketing Information

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

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K965017	02/07/2006	

**Labeler** - Smiths Medical ASD, Inc. (137835299)

### Establishment

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

### Establishment

Name	Address	ID/FEI	Business Operations
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Aplicare, Inc.		107255002	manufacture
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Revised: 7/2016

Smiths Medical ASD, Inc.