

A3382-18 S.A.S. SINGLE SHOT EPIDURAL - regional anesthesia kit
Smiths Medical ASD, Inc.

APLICARE POVIDONE-IODINE SOLUTION (povidone-iodine solution) solution
[Aplicare, Inc.]

3/4 Ounce Povidone Iodine Packet

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.

Package Label Display Panel

NDC 52380-0001-3
DIN 02076144

TEAR HERE
POUR



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	
Do not use if allergic to iodine	
For external use only	

Reorder No. L-3001

A 7K022 EXP 10-10

TEAR HERE
POUR

Drug Facts (continued)

Warnings

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

Do not use in eyes

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.

Directions apply locally as needed

Other information

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

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

Questions or comments?

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



APLICARE, INC.
MERIDEN, CT 06450
U.S.A.

DOLLARD-des-ORMEAUX,
QUEBEC H9G 2S3
www.aplicare.com
0407

Package Label Display Panel



REF A3382-18

PORTEX®

**"S.A.S." SINGLE SHOT EPIDURAL
18G TUOHY****PROCEDURAL COMPONENTS:**

- 1 Tuohy Epidural Needle Calibrated with Wings (18G x 3 1/2 in. T.W.)
- 1 Glass L.O.R. Syringe (5ml, Metal Luer Lock)
- 1 18G x 1 1/2 in. Needle
- 1 27G x 1 1/2 in. T.W. Needle
- 1 Plastic Syringe (10ml, Luer Lock)
- 1 Plastic Syringe (3ml, Luer Lock)
- 1 Fenestrated Drape

PREP COMPONENTS:

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

WARNING(S):

- A needle stick with a contaminated needle may cause infectious disease.

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.
- To be used only by individuals familiar with single shot epidural procedures. For specific techniques and procedures, refer to standard textbooks.

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(01) 0 0351688 06905 7



STERILE EO Rx ONLY

Caution • Do Not Reuse • Does not contain Natural Rubber Latex • Do not use if package is damaged • Sterilized using ethylene oxide • **Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician

STERILITY:
Contents within CSR wrap are sterile unless the CSR wrap is opened or damaged.

Smiths Medical ASD, Inc.
Keene, NH 03431 USA
Made in USA

www.smiths-medical.com

PLA3382-18 REV. 004 10/11

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smiths medical

PORTEX®

"S.A.S."
SINGLE SHOT EPIDURAL
18G TUOHY

REF A3382-18



Use By: 0000-00

yyyy-mm

LOT 000000

LOT

smiths medical

A3382-18 S.A.S. SINGLE SHOT EPIDURAL

regional anesthesia kit kit

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:51688-9844
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:51688-9844-2	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 1 of 1**APLICARE POVIDONE-IODINE**

povidone-iodine solution

Product Information

Item Code (Source)	NDC:52380-0001
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Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	POVIDONE-IODINE	0.10 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		

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	02/06/2006	

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