

**A2659-18 SINGLE SHOT EPIDURAL 18G TUOHY - 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 A2659-18
SINGLE SHOT EPIDURAL
18G TUOHY



PROCEDURAL COMPONENTS:

- 1 Tuohy Epidural Needle Calibrated with Wings (18G x 3 1/2 in. TW)
- 1 Pulsator® L.O.R. Syringe (7ml, Luer Slip)
- 1 18G x 1 1/2 in. Needle
- 1 25G x 1 1/2 in. Needle
- 1 Medicine Cup & Cover, 50ml
- 2 Plastic Syringes (10ml, Luer Lock)
- 2 Plastic Syringes (5ml, Luer Lock)
- 2 Plastic Syringes (3ml, Luer Lock)
- 1 Adhesive Bandage
- 4 Gauze Sponges
- 1 Fenestrated Drape with 4 Tabs

PREP COMPONENTS:

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


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.

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




STERILE EO

Rx ONLY

© 2010 Smiths Medical family of companies. All rights reserved.

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

PTA2659-18 REV. 001 10/10



(01) 0 0351688 06218 8

REF A2659-18

SMITHS MEDICAL

Use by: 0000-00

A2659-18 SINGLE SHOT EPIDURAL 18G TUOHY

regional anesthesia kit kit

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:51688-9059
---------------------	----------------	---------------------------	------------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:51688-9059-2	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

APPLICARE 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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K965017	12/14/2005	

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