A2628 NERVE BLOCK - 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



Package Label Display Panel



PORTEX

- PROCEDURAL COMPONENTS:

 1 Extension Set (7 in. Microbore) with Slide Clamp

 2 18 cx 1 ½ in. Needles

 2 25 cx 1 ½ in. Needle

 1 Plastic Control Syringe (10ml, Luer Lock)

 1 Plastic Syringe (10ml, Luer Slip)

 4 Gauze Sponges

 1 Clear Fenestrated Drape

 PREP COMPONENTS:

 3 Sponge Applicators

 1 Povidone-Iodine Solution, ¾ oz.

- WARNING(S):

 A needle citck 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, based-sharp is an suitable-sharps container. Dispose of contaminated product. 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 nerve block procedures. For specific techniques and procedures, refer to standard textbooks.

The Smiths Medical and Portex design marks 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.







101

smiths medical

00-0000



ww.smiths-medical.com

PTA2628 REV. 001 10/10



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

smiths medical

A2628 NERVE BLOCK

regional anesthesia kit kit

Product Information

Product Type MEDICAL DEVICE NHRIC:51688-8637 Item Code (Source)

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NHRIC:51688-8637-2	10 in 1 CASE		
1	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts Part# **Package Quantity Total Product Quantity** 22.5 mL Part 1 1 PACKET

Part 1 of 1

APLICARE POVIDONE-IODINE

povidone-iodine solution

Product Information		
Item Code (Source)	NDC:52380-0001	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PO VIDO NE-IO DINE (IO DINE)	PO VIDONE-IO DINE	0.10 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
CITRIC ACID MO NO HYDRATE				
SO DIUM PHO SPHATE, DIBASIC				
SO DIUM HYDRO XIDE				
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

Revised: 11/2012 Smiths Medical ASD, Inc.