A3553 REGIONAL 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

REF A3553 **REGIONAL BLOCK**

PORTEX

PROCEDURAL COMPONENTS:

- Clear Fenestrated Drape 18G x 1 ½ in. Needles
- 25G x 1 1/2 in. Needle
- Plastic Syringe (10ml, Luer Lock)
 Plastic Syringe (5ml, Luer Lock)
 Plastic Syringe (3ml, Luer Lock)
 Needle Stick Pad

PREP COMPONENTS:

- Sponge Applicators Gauze Sponges
- Povidone-Iodine Solution, ¾ oz. Towel

- WARNING(5):

 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.

- Use Asseptic 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 regional 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 \circledast indicates the trademark is registered in the U.S. Patent and Trademark Office and certain other countries.

STERILE EO RX





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

smiths medical



REGIONAL BLOCK

smiths medical

Use By:

 \square

yyyy-mm

101

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

www.smiths-medical.com

PLA3553 REV. 001 01/11

A3553 REGIONAL BLOCK

regional anesthesia kit kit

Product Information

Product Type MEDICAL DEVICE Item Code (Source) NHRIC:51688-5247

Caution • Do Not Reuse • Latex Free • 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

© 2011 Smiths Medical family of companies. All rights reserved

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:51688-5247-2	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			
Route of Administration	TOPICAL	DEA Schedule		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
PO VIDO NE-IO DINE (IO DINE)	POVIDONE-IODINE	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				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
part333A	03/01/1984			
A	Application Number or Monograph Citation	Application Number or Monograph Citation Marketing Start Date		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
premarket notification	K965017	0 1/2 1/2 0 0 8		

Labeler - Smiths Medical ASD, Inc. (137835299)

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

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

Revised: 9/2012 Smiths Medical ASD, Inc.