

**A3129-17 PORTEX SINGLE SHOT EPIDURAL- anesthesia conduction kit
Smiths Medical ASD, Inc.**

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

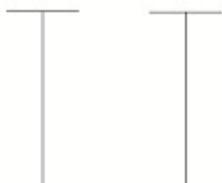
1 800 760-3236 (Mon to Fri 8:30 AM-5:00 PM EST)

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

Do not use ■ if allergic to iodine ■ in the eyes

For external use only

Reorder No. L-3001

APLICARE, INC.
MERIDEN, CT 06450
U.S.A.
DOLLARD-des-ORMEAUX,
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0609

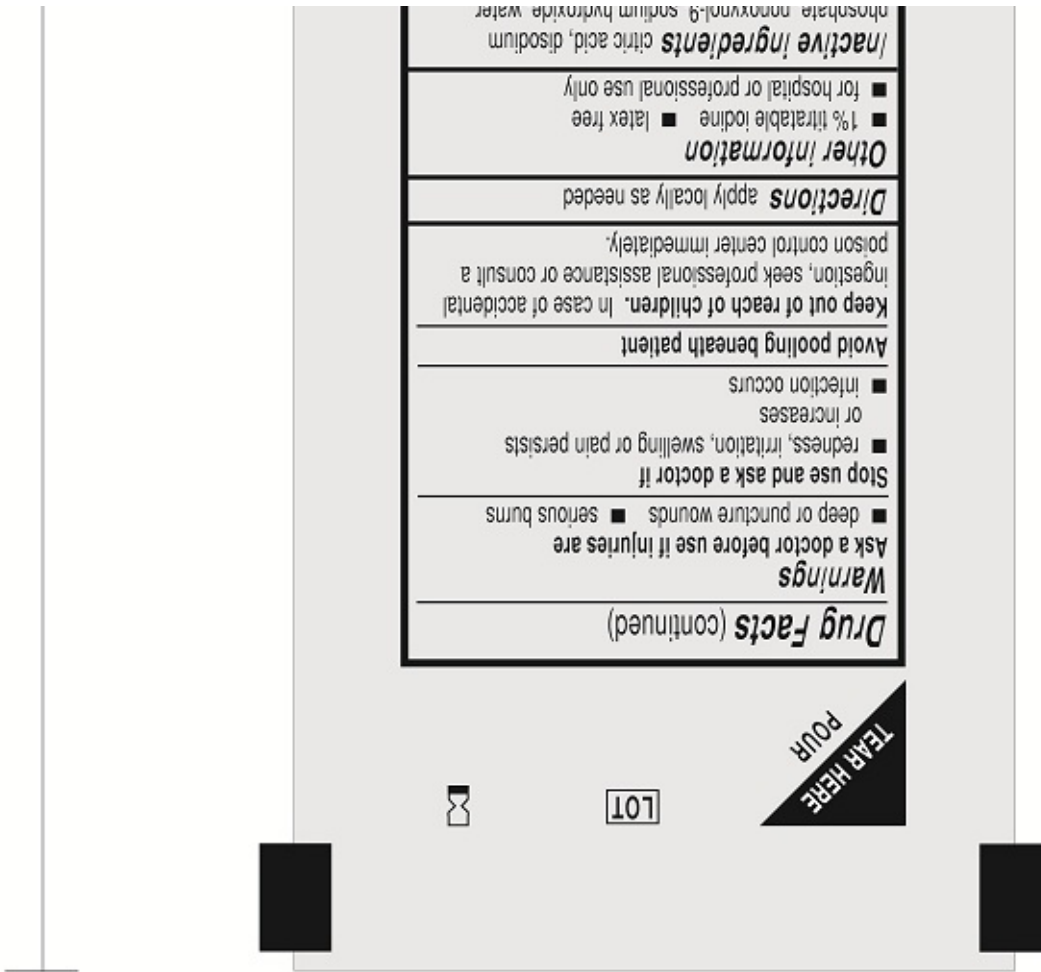


(01) 0 0352380 00013 3

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

PORTEX® SINGLE SHOT EPIDURAL 17G TUOHY

REF A3129-17

PROCEDURAL COMPONENTS:

- 1 Tuohy Epidural Needle Calibrated with Wings (17G x 3 1/4 in. T.W)
 - 1 18G x 1 1/2 in. Needle
 - 1 25G x 1 1/2 in. Needle
 - 1 Pulator® L.O.R. Syringe (7ml, Luer Slip)
 - 1 Plastic Syringe (20ml, Luer Lock)
 - 1 Plastic Syringe (2ml, Luer Lock)
 - 1 Needle Jack Pad
 - 1 Transparent Dressing
 - 1 Clear Fanestrated Drape
- ### PREP COMPONENTS:
- 5 Gacia Sponges
 - 1 Towel
 - 3 Sponge Applicators
 - 1 Povidone-Iodine Solution, 1/2 oz.

WARNINGS:

- As with all plastic wrapped products, do not open or unwrap in areas where static electric discharge may be hazardous due to risk of explosion.
- 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 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 Sterilize.
- 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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REF SLUG 2D

smiths

Manufacturer:
Smiths Medical ASD, Inc.
10 Bowman Drive
Kennebunk, NH 03431 USA
www.smiths-medical.com
MADE IN USA



Attention, see instructions for use. Do Not Reuse. Latex Free. Do not use if packages is damaged. Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Sterilized using ethylene oxide.

PLT3129-17 REV:002 04/16

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A3129-17 PORTEX SINGLE SHOT EPIDURAL

anesthesia conduction kit kit

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:51688-9616
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:51688-9616-2	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

APLICARE 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	12/14/2005	

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
Aplicare, Inc.		107255002	manufacture

Revised: 10/2016

Smiths Medical ASD, Inc.