ACL11SP NERVE BLOCK - regional anesthesia kit Clint Pharmaceuticals, 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 ACL11SP

To Reorder Call: 1-800-677-5022

PREP COMPONENTS:

- Towel
 Povidone-Iodine Solution, ¾ o:
- Sponge Applicators Gauze Sponges

PROCEDURAL COMPONENTS:

- Fenestrated Drape
- 18G X 1 ½ In. Needle
- 1 25G X 1 ½ In. Needle 1 Plastic Syringe (10ml, Luer Loc
- Plastic Syringe (5ml, Luer Lock)
 Plastic Syringes (3ml, Luer Lock)

NERVE BLOCK

WARMINGS:
A needle stick with a contaminated needle may cause infectious disease.
The use of axcessive force while placing needles into the stick pad may cause the needle to protrude through the bottom of operating result in a contaminated needle sting.

Sept. 4111006.

- Use Asseptic technique.
 To help prevent needle stick injuries, needles should not be recapped or purposely bent. If excessive resists needle insertion, do not force the needle as damage may occur. To help avoid needle breakage, do not attern bent needle; discard it and complete the procedure with a replacement needle.
- Neter look, place and pis in a satisface sharps containing to center not place as Control and Prevention, USA and Federal/State/Local regulations (EPA, OSHA) and health care facility guidelines or local equivalent.
 Do NOT Resterilize.

Manufactured for: Clint Pharmaceuticals 629 Shute Lane Old Hickory, TN 37138



Made in USA

PLTACL11SP REV. 002 09



REF ACL11SP

To Reorder Call: 1-800-677-5022

PREP COMPONENTS:

- Towel
 Povidone-Iodine Solution, ¾ oz.
- Povidone-lodine Solution, № oz
 Sponge Applicators

PROCEDURAL COMPONENTS:

- Fenestrated Drape Needle Stick Pad
- 18G X 1 ½ In. Needle
- 25G X 1 ½ In. Needle Plastic Syringe (10ml, Luer Lock
- 1 Plastic Syringe (5ml, Luer Lock

NERVE BLOCK

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 tray which may result in a contaminated needle stick.

- Use Aseptic technique.
 To help prevent needle-stick injuries, needles should not be recapped or purposely bent. If excessive resistance is met durin
 needle insertion, do not force the needle as damage may occur. To help avoid needle breaking, do not attempt to straighten
 bent needle discard trait on complete the procedure with a replacement needle.
 Content to the content of the conten
- Do NOT Resterilize.
 To be used only by individuals familiar with nerve block procedures. For specific techniques and procedures, refer to standar

Manufactured for: Clint Pharmaceuticals 629 Shute Lane Old Hickory, TN 37138

Marketing Start Date



in USA PLTACL 11SP REV

ACL11SP NERVE BLOCK

regional anesthesia kit kit

Product Information

Product Type MEDICAL DEVICE Item Code (Source) NHRIC:55553-436

Packaging # Item Code Package Description

1 NHRIC:55553-436-02 30 in 1 CASE 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



Marketing End Date

Product Information		
Item Code (Source)	NDC:52380-0001	
Route of Administration	TOPICAL	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PO VIDO NE-IO DINE (UNII: 85H0 HZU99M) (IO DINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
SO DIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
NONOXYNOL-9 (UNII: 48Q180SH9T)		
WATER (UNII: 059QF0KO0R)		

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 - Clint Pharmaceuticals, Inc. (609197785)

Registrant - 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: 6/2013 Clint Pharmaceuticals, Inc.