ACL14 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



PROCEDURAL COMPONENTS:

REF ACL14

To Reorder Call: 1-800-677-5022

PREP COMPONENTS:

NERVE BLOCK

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



PLTACL14 REV: 001 01/11



PROCEDURAL COMPONENTS:

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To Reorder Call: 1-800-677-5022

PREP COMPONENTS:

NERVE BLOCK



Manufactured for: **Clint Pharmaceuticals** 629 Shute Lane Old Hickory, TN 37138 Made In USA



PLTACL14 REV: 001 01/11

ACL14 NERVE BLOCK

regional anesthesia kit kit

Product Information

MEDICAL DEVICE NHRIC:55553-469 Product Type Item Code (Source)

Packaging Item Code Package Description **Marketing Start Date Marketing End Date** 1 NHRIC:55553-469-02 30 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	
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)	PO VIDO NE-IO DINE	0.10 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	11/16/2010		

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: 6/2012 Clint Pharmaceuticals, Inc.