ACS25Q35 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





To Reorder Call: 1-800-677-5022

PREP COMPONENTS:

PROCEDURAL COMPONENTS:

NERVE BLOCK

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





REF ACS25Q35

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ACS25Q35 NERVE BLOCK

regional anesthesia kit kit

Product Information

MEDICAL DEVICE Item Code (Source) NHRIC:55553-461 Product Type

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NHRIC:55553-461-02	30 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	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PO VIDO NE-IO DINE (UNII: 85H0 HZU99 M) (IO DINE - UNII:9679 TC07X4)	POVIDONE-IODINE	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)			

P	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	09/19/2006		

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.