ACL11KC 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





NERVE BLOCK

PREP COMPONENTS

- Towel Povidone-lodine Solution, ¾ oz.
- 3 Sponge Applicators
 PROCEDURAL COMPONENTS:

- Fenestrated Drape
- Gauze Sponges 18G x 1 ½ in. Needle
- 25G x 2 in. Needle 30G x 1 in. Needle
- Plastic Syringe (10ml, Luer Lock) Plastic Syringe (5ml, Luer Lock)
- Plastic Syringes (3ml, Luer Lock)
- Needle Stick Pad

- 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.
 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.
- 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 nerve block procedures. For specific techniques and procedures, refer to standard textbooks.

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NERVE BLOCK

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

Caution • Do Not Reuse • Does not contain Natural Rubber Latex • 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

↑ ② ♥ STERILE EO RX ONLY

PTACL11KC REV. 002 09/11

ACL11KC NERVE BLOCK

regional anesthesia kit kit

Product Information

NHRIC:55553-435 Product Type MEDICAL DEVICE Item Code (Source)

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NHRIC:55553-435-02	24 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

	8		
Ingredient Name		Basis of Strength	Strength
	PO VIDO NE-IO DINE (UNII: 85H0 HZU99 M) (IO DINE - UNII:9679 TC07X4)	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
ı	1 NDC:52380-0001-3	22.5 mL in 1 PACKET		

Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC monograph not finalpart333A03/01/1984

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.