

ACL12 REGIONAL ANESTHESIA PREP TRAY - regional anesthesia kit
Clint Pharmaceuticals, Inc.

Drug Facts

APLICARE THREE POVIDONE-IODINE SWABSTICKS
[Aplicare, Inc.]

Three 4-inch saturated swabsticks

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.

NDC 52380-3101-5

NPN 02076101



← Tear Here Hold Upright Tear Here →

THREE

POVIDONE-IODINE SWABSTICKS

Three 4-inch saturated swabsticks

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 or in the eyes

For external use only

Reorder No. S-3101

APLICARE EXP-01 2015

LOT

Drug Facts (continued)

Warnings

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.

Directions apply locally as needed

Other information

■ 1% available iodine ■ latex free
■ for hospital or professional use only

Inactive ingredients citric acid, dicalcium phosphate, nonoxonyl-9, sodium hydroxide, water

For questions, comments, or to report serious side effects:

1-800-760-3236

Monday - Friday 8:30 a.m. - 5:00 p.m. EST



APLICARE, INC.
MERIDEN, CT 06450
U.S.A.
DOLLARD-des-ORMEAUX
QUEBEC H9G 2S3
www.aplicare.com
1209

Package Label Display Panel

To Reorder Call:
1-800-677-5022

REF **ACL12**

CONTENTS:

- 1 - TRAY
- 1 - IODOPHOR PVP SWABSTICK, 3'S
- 4 - GAUZE SPONGES
- 1 - TOWEL
- 1 - FENESTRATED DRAPE

LOT

USE BY:

REV. 07/05



(01) 0 0351688 06408 3

CLINT.
PHARMACEUTICALS
INCORPORATED

**REGIONAL ANESTHESIA
PREP TRAY**

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

Made in USA

AR339 REV. 001

CAUTION:

Follow standard infection control procedures as specified by the Centers for Disease Control and Prevention (USA) or local equivalent.



Rx ONLY

STERILE EO

Attention, see instruction for use. Do Not Reuse. Latex Free. Do not use if package 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; the contents within the CSR wrap are sterile unless the CSR wrap is opened or damaged.

ACL12 REGIONAL ANESTHESIA PREP TRAY

regional anesthesia kit kit

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:55553-438
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:55553-438-02	10 in 1 CASE		
1		1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	6.5 mL

Part 1 of 1

APLICARE POVIDONE-IODINE TRIPLES

povidone-iodine solution

Product Information

Item Code (Source) NDC:52380-3101

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	POVIDONE-IODINE	9.8 g in 96.4 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380-3101-5	6.5 mL in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/01/1998	

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: 6/2012

Clint Pharmaceuticals, Inc.