

**ACL10 SINGLE SHOT EPIDURAL - 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  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



REF ACL10

To Reorder Call:  
1-800-677-5022

- PREP COMPONENTS:**
- 1 Towel
  - 1 Iodophor PVP Swabstick, 3's
  - 3 Gauze Sponges

- PROCEDURAL COMPONENTS:**
- 1 Fenestrated Drape
  - 1 Needle Stick Pad
  - 1 18G X 1 1/2 In. Needle
  - 1 25G X 1 1/2 In. Needle
  - 1 Pulstar® L.O.R. Syringe (7ml, Luer Slip)
  - 1 Plastic Syringe (10ml, Luer Lock)
  - 1 Plastic Syringe (5ml, Luer Lock)
  - 2 Plastic Syringes (3ml, Luer Lock)

### SINGLE SHOT EPIDURAL

**WARNINGS:**

- 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 box which may result in a contaminated needle stick.

**PRECAUTIONS:**

- Use **Aspic 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.
- 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 Sterilize.
- To be used only by individuals familiar with single shot epidural procedures. For specific techniques and procedures, refer to standard textbooks.

Pulstar is a trademark of Smiths Medical. The symbol ® indicates the trademark is registered in the U.S. Patent and Trademark Office and certain other countries.

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



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

Made in USA

PLTACL10 REV.002 09/11



(01) 0 0351688 06325 3



REF ACL10

To Reorder Call:  
1-800-677-5022

- PREP COMPONENTS:**
- 1 Towel
  - 1 Iodophor PVP Swabstick, 3's
  - 3 Gauze Sponges

- PROCEDURAL COMPONENTS:**
- 1 Fenestrated Drape
  - 1 Needle Stick Pad
  - 1 18G X 1 1/2 In. Needle
  - 1 25G X 1 1/2 In. Needle
  - 1 Pulstar® L.O.R. Syringe (7ml, Luer Slip)
  - 1 Plastic Syringe (10ml, Luer Lock)
  - 1 Plastic Syringe (5ml, Luer Lock)
  - 2 Plastic Syringes (3ml, Luer Lock)

### SINGLE SHOT EPIDURAL

**WARNINGS:**

- 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 box which may result in a contaminated needle stick.

**PRECAUTIONS:**

- Use **Aspic 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.
- 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 Sterilize.
- To be used only by individuals familiar with single shot epidural procedures. For specific techniques and procedures, refer to standard textbooks.

Pulstar is a trademark of Smiths Medical. The symbol ® indicates the trademark is registered in the U.S. Patent and Trademark Office and certain other countries.

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



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

Made in USA

PLTACL10 REV.002 09/11



(01) 0 0351688 06325 3

## ACL10 SINGLE SHOT EPIDURAL

regional anesthesia kit kit

### Product Information

<b>Product Type</b>	MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:55553-429
---------------------	----------------	---------------------------	-----------------

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:55553-429-02	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: 059QF0KO0R)	

**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: 5/2012

Clint Pharmaceuticals, Inc.