

**ACL10SPSL SINGLE SHOT EPIDURAL - regional anesthesia kit**  
**Clint Pharmaceuticals, Inc.**

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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

NDC 52380-0001-3  
DIN 02076144

TEAR HERE  
POUR



**3/4 FLUID OUNCE**  
**POVIDONE-IODINE**  
**SOLUTION**

0.75 Fl. oz. (22.5 mL)

**STERILE** unless opened or damaged.

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Povidone-iodine USP 10%	Antiseptic
<b>Use</b> antiseptic skin preparation	
<b>Warnings</b>	
Do not use if allergic to iodine	
For external use only	

Reorder No. L-3001

EXP 10-10

TEAR HERE  
POUR

<b>Drug Facts (continued)</b>
<b>Warnings</b>
Ask a doctor before use if injuries are ■ deep or puncture wounds ■ serious burns
<b>Stop use and ask a doctor if</b>
■ redness, irritation, swelling or pain persists or increases ■ infection occurs
<b>Do not use in eyes</b>
<b>Avoid pooling beneath patient</b>
Keep out of reach of children. In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.
<b>Directions</b> apply locally as needed
<b>Other information</b>
■ 1% titratable iodine ■ latex free ■ for hospital or professional use only
<b>Inactive ingredients</b> citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water
<b>Questions or comments?</b>
☎ 1-800-760-3236 (Mon to Fri 8:30 AM-5:00 PM EST)



APLICARE, INC.  
MERIDEN, CT 06450  
U.S.A.  
DOLLARD-des-ORMEAUX,  
QUEBEC H9G 2S3  
www.aplicare.com  
0407

Package Label Display Panel



REF ACL10SPSL

To Reorder Call:  
1-800-677-5022

**PROCEDURAL COMPONENTS:**

- 1 Pulator® L.O.R. Syringe (7ml, Luer Lock)
- 1 36 in. Extension Set
- 1 Needle-Pro® Device with 18G x 1 1/2 in. Needle (Attached)
- 1 Needle-Pro® Device with 25G x 1 1/2 in. Needle (Attached)
- 1 Plastic Syringe (10ml, Luer Lock)
- 1 Plastic Syringe (5ml, Luer Lock)
- 2 Plastic Syringes (3ml, Luer Lock)
- 1 Needle Stick Pad
- 1 Medication Label
- 1 Clear Fenestrated Drape

**PREP COMPONENTS:**

- 3 Sponge Applicators
- 1 Towel
- 4 Gauze Sponges
- 1 Povidone-Iodine Solution, 1/2 oz.

**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 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.
  - 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.
- Pulator, Needle-Pro and the color orange applied to the needle protection device are trademarks of the Smiths Medical family of companies. 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



Packaged in USA with US and Imported parts

PLTACL10SPSL REV. 003 01/11



(01) 2 0351688 07448 2



REF ACL10SPSL

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# ACL10SPSL SINGLE SHOT EPIDURAL

regional anesthesia kit kit

## Product Information

<b>Product Type</b>	MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:55553-433
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:55553-433-02	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
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Route of Administration	TOPICAL
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**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

**Inactive Ingredients**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380-0001-3	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	01/21/2009	

**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
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Aplicare, Inc.

107255002

manufacture

Revised: 6/2013

Clint Pharmaceuticals, Inc.