

ACL10SPS12 SINGLE SHOT EPIDURAL - 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

NDC 52380-0001-3
DIN 02076144

TEAR HERE
POUR

APLICARE®

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

0.75 Fl. oz. (22.5 mL)

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	
For external use only	

Reorder No. L-3001

A 7K022 EXP 10-10

TEAR HERE
POUR

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
Do not use in eyes
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% titratable iodine ■ latex free ■ for hospital or professional use only
Inactive ingredients citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water
Questions or comments?
☎ 1-800-760-3236 (Mon to Fri 8:30 AM-5:00 PM EST)

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

Package Label Display Panel



REF ACL10SPS12

To Reorder Call:
1-800-677-5022

PROCEDURAL COMPONENTS:

- 1 Pulator® L.O.R. Syringe (7ml, Luer Slip)
- 1 12 in. Microbore Extension Set with Clamp
- 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% 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 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



Made in USA

PJTACL10SPS12 REV. 000 04/12



(01) 2 0351 6888 07953 1



REF ACL10SPS12

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1-800-677-5022

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(01) 2 0351 6888 07953 1

ACL10SPS12 SINGLE SHOT EPIDURAL

regional anesthesia kit kit

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:55553-477
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:55553-477-02	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

APPLICARE 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)	POVIDONE-IODINE	0.10 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	04/18/2012	

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: 9/2012

Clint Pharmaceuticals, Inc.