

ACL5SP 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

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

EXP 10-10

Drug Facts (continued)

Warnings

Ask a doctor before use if injuries are

- deep or puncture wounds
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Stop use and ask a doctor if

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Do not use in eyes

Avoid pooling beneath patient

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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)

0352380 00013 3
(01) 0 0352380 00013 3

APLICARE, INC.
MERIDEN, CT 06450
U.S.A.

DOLLARD-des-ORMEAUX,
QUEBEC H9G 2S3
www.aplicare.com
0407

Package Label Display Panel



REF ACL5SP

To Reorder Call:
1-800-677-5022

- PREP COMPONENTS:**
- 1 Towel
 - 1 Povidone-Iodine Solution, ¼ oz.
 - 3 Sponge Applicators
 - 5 Gauze Sponges

- PROCEDURAL COMPONENTS:**
- 1 Fenestrated Drape
 - 1 Needle Stick Pad
 - 1 18G x 1 ½ in. Needle
 - 1 25G x 1 ½ in. Needle
 - 1 Tuohy Epidural Needle Calibrated with Wings (18G x 3 ½ in.)
 - 1 Pulvator® L.O.R. Syringe (7ml, Luer Slip)
 - 1 Plastic Syringe (10ml, Luer Lock)
 - 1 Plastic Syringe (3ml, 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 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 (BPA, OSHA) and health care facility guidelines or local equivalent.
 - Do NOT reuse.
 - To be used only by individuals familiar with single shot epidural procedures. For specific techniques and procedures, refer to standard textbooks.

Pulvator 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

Made in USA

STERILE EO Rx ONLY

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

PTACL5SP REV. 002 11/11



(01) 0 0351688 06725 1



REF ACL5SP

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(01) 0 0351688 06725 1

ACL5SP SINGLE SHOT EPIDURAL

regional anesthesia kit kit

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:55553-448
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:55553-448-02	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	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
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Aplicare, Inc.

107255002

manufacture

Revised: 6/2012

Clint Pharmaceuticals, Inc.