

ACL10SPG 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



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)



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

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

Package Label Display Panel

SSE SINGLE SHOT EPIDURAL

REF ACL10SPG

To Reorder Call: 1-800-677-5022

PROCEDURAL COMPONENTS:

- 1 Fenestrated Drape
- 4 Gauze Sponges
- 1 18G x 1 1/2 in. Needle
- 1 25G x 1 1/2 in. Needle
- 1 Needle Stick Pad
- 1 Glass L.O.R. Syringe (5ml, Luer Slip)
- 1 Plastic Syringe (10ml, Luer Lock)
- 1 Plastic Syringe (5ml, Luer Lock)
- 2 Plastic Syringes (3ml, Luer Lock)

PREP COMPONENTS:

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

WARNING(S):

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



(01) 0 0351688 06949 1



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



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

PTACL10SPG REV.001 09/11

SSE SINGLE SHOT EPIDURAL



REF ACL10SPG

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LOT 000000



ACL10SPG SINGLE SHOT EPIDURAL

regional anesthesia kit kit

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:55553-431
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:55553-431-02	10 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

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 mono graph not final	part333A	03/01/1984	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K965017	05/05/2006	

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