

ACL4SP SINGLE SHOT EPIDURAL - regional anesthesia kit
Clint Pharmaceuticals, Inc.

Drug Facts

Povidone-iodine

Antiseptic

Antiseptic skin preparation

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

Avoid excessive heat. Store at room temperature.

Keep out of reach of children

In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.

Apply locally as needed.

1% titratable iodine latex free for hospital or professional use only

citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water

1 800 760-3236 (Mon to Fri 8:30 AM-5:00 PM EST)

Package Label Display Panel





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 ■ in the eyes

For external use only ▶

Reorder No. L-3001

APLICARE, INC.
MERIDEN, CT 06450
U.S.A.
DOLLARD-des-ORMEAUX,
QUEBEC H9G 2S3
www.aplicare.com
0609



Questions or comments?
☎ 1 800 760-3236 (Mon to Fri 8:30 AM-5:00 PM EST)

Inactive ingredients citric acid, disodium phosphate, nonoxonyl-9, sodium hydroxide, water

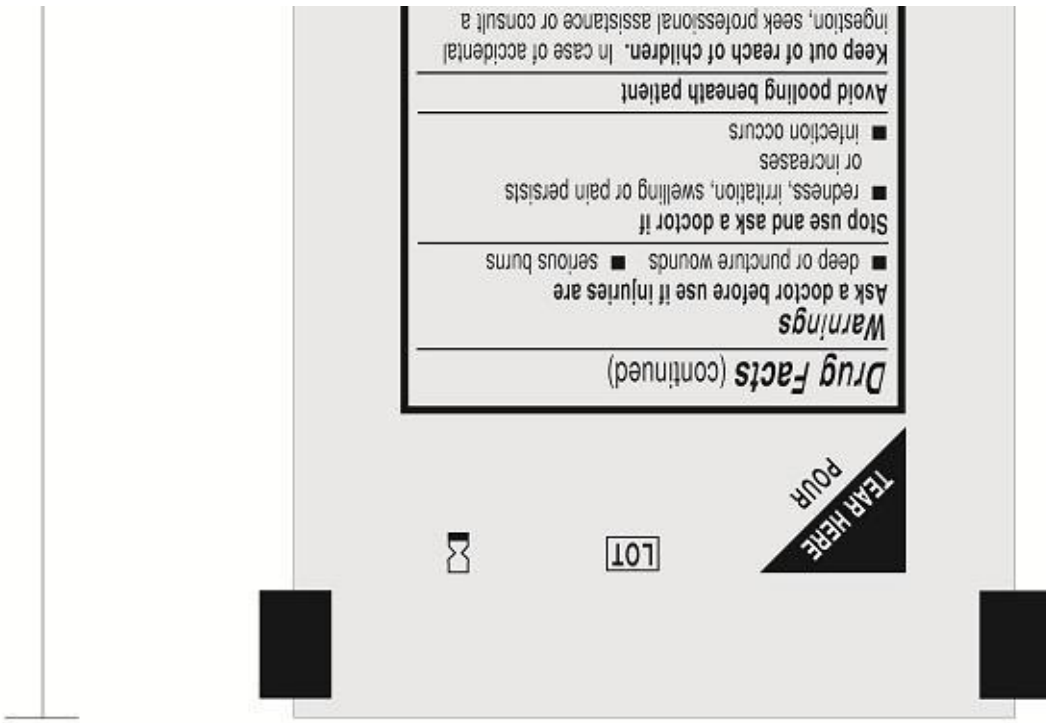
Other information
■ 1% titratable iodine ■ latex free
■ for hospital or professional use only

Directions apply locally as needed

poison control center immediately.

5.375"

10.75"



Package Label Display Panel

CLINT
PHARMACEUTICALS
I N C O R P O R A T E D

REF ACL4SP

To Reorder Call:
1-800-677-5022

PREP COMPONENTS:

- 1 Towel
- 1 Povidone-Iodine Solution, ¼ oz.
- 3 Sponge Applicators
- 4 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 Huscod Epidual Needle - Calibrated with Wings (20G x 3 ½ in.)
- 1 Pulfator® L.O.R. Syringe (7ml, Luer Lock)
- 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 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, DSHA) and health care facility guidelines or local equivalent.
- Do NOT Reuse/sterilize.
- To be used only by individuals familiar with single shot epidural procedures. For specific techniques and procedures, refer to standard textbooks.

Pulfator 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



PLTACL4SP REV. 003 11/11



CLINT
PHARMACEUTICALS
I N C O R P O R A T E D

REF ACL4SP

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1-800-677-5022

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ACL4SP SINGLE SHOT EPIDURAL

regional anesthesia kit kit

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:55553-445
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:55553-445-02	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
Route of Administration	TOPICAL

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
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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	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Aplicare, Inc.		107255002	manufacture

Revised: 4/2015

Clint Pharmaceuticals, Inc.