

ACL13KC 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

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



REF ACL13KC

To Reorder Call:
1-800-677-5022

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

- PROCEDURAL COMPONENTS:**
- 1 Fenestrated Drape
 - 1 Needle Stick Pad
 - 1 18G x 1 ½ in. Needle
 - 1 22G x 1 ½ in. Needle
 - 1 25G x 1 in. Needle
 - 1 Husted Epidural Needle (18G x 3 ½ in. X.T.W)
 - 1 Glass L.O.R. Syringe (5mL, Luer Slip)
 - 1 Plastic Syringe (10mL, Luer Lock)
 - 1 Plastic Syringe (3mL, Luer Lock)

SINGLE SHOT EPIDURAL

WARNINGS:

- As with all plastic wrapped products do not open or unwrap in areas where static electric discharge may be hazardous, due to risk of explosion.
- 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, OSHA, 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 methods.

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



Made in USA

PLTACL13KC REV. 001



(01) 0 0351688 06822 7



REF ACL13KC

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ACL13KC SINGLE SHOT EPIDURAL

regional anesthesia kit kit

Product Information

| | | | |
|---------------------|----------------|---------------------------|-----------------|
| Product Type | MEDICAL DEVICE | Item Code (Source) | NHRIC:55553-439 |
|---------------------|----------------|---------------------------|-----------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|--------------------|-----------------------------|----------------------|--------------------|
| 1 | NHRIC:55553-439-02 | 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 |
|--------------------|----------------|

| | |
|-------------------------|---------|
| 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 |
|-------------------------|--|----------------------|--------------------|
| 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 |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

Aplicare, Inc.

107255002

manufacture

Revised: 6/2013

Clint Pharmaceuticals, Inc.