

**TUN-L-XL 191-2540- catheter, conduction, anesthetic
Epimed International**

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

Epimed

INTERNATIONAL, Inc.

Johnstown, NY 12095 USA 800-866-3342 or 518-725-0209 Fax: 518-725-0207

REF:
199-2340

WILEY SPINAL™

STERILE EO
Non-pyrogenic

Contents:

- 1 (One) Wiley-Spinal™
- 1 (One) Extension Set with Wik-Wire™
- 1 (One) 2Fr Peel-Away Introducer
- 1 (One) Syringe 3cc Plastic Luer Lock
- 1 (One) Syringe 6cc Plastic Luer Lock
- 1 (One) 18g x 1.5" Infiltration Needle
- 1 (One) 25g x 1.5" Skin Wheel Needle
- 1 (One) 18g x 1.5" Filter Needle
- 1 (One) Epidural Flat Filter
- 1 (One) Insertion Site Support Pad
- 1 (One) Tegaderm™ Transparent Dressing
- 1 (One) Iodophor Swabsticks PVP (3)
- 1 (One) Drape, Clear 24" x 32", 4" Round Fenestration
- 1 (One) Towel, White 18" x 18"
- 5 (Five) Gauze Sponges 3" x 3"



Intended for the administration of anesthetic agents to provide regional anesthesia.
WARNING: NOT APPROVED FOR USE WITH CONTINUOUS INFUSION PUMPS.

DO NOT USE WITH OTHER INTRODUCERS.

**DO NOT USE MAGNETIC RESONANCE IMAGING WHILE THIS
DEVICE IS IN PLACE WITHIN THE PATIENT.**

PRECAUTION: NOT FOR USE WITH HYPERBARIC SOLUTIONS.

Caution: Federal (U.S.A) Law Restricts This Device To Sale By Or On The Order Of A Physician.
Disposable For Single Use Only.

Sterility: Contents Within The Enclosed Sealed Package Are Sterile Unless Package Has Been
Opened Or Damaged.



Item Number



0000 - 00



Quantity



HIBCC

LOT sample



32°C
10°C

+M81719923400L+

Tegaderm is a trademark of 3M

Wiley Spinal™ and Wik-Wire™ are trademarks of Epimed International, Inc.
Patents Pending LA- 645 Rev. 1

TUN-L-XL 191-2540

catheter, conduction, anesthetic kit

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:60816-2540
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:60816-2540-1	1 in 1 PACKAGE		

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		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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K954584	10/08/1996	

Labeler - Epimed International (799751953)

Establishment

Name	Address	ID/FEI	Business Operations
Epimed International		799751953	relabel, manufacture

Establishment

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

Revised: 9/2013

Epimed International