LORIS POVIDONE-IODINE SOLUTION- povidone-iodine liquid LernaPharm Loris Inc.

Drug Facts

Active Ingredients

Povidone Iodine 10% w/v

Purpose

Antiseptic

Uses

For preparation of the skin prior to surgery. Helps reduce bacteria that potentially can cause skin infection.

Warnings

For External Use Only

- Do not use in the eyes.
- Discontinue use if irritation and redness develop.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Clean the area.
- Apply product to the operative site prior to surgery.
- Apply with friction for 30 seconds.
- Do not blot or wipe away.

Other Information

Store at room temperature between 59-86 °F (15-30 °C). 1% titratable iodine. Latex free

Inactive Ingredients

Citric Acid, Glycerol, Nonoxynol-9, Purified Water, Sodium Hydroxide, Sodium Phosphate Dibasic

Questions or comments?

Call 1-866-322-4634, weekdays between 8:00 am and 6:00 pm EST

Principal Display Panel

Hold upright

Product # 119-XXU NDC: 68356-119-XX

Loris Povidone-Iodine [Solution]

[TEAR OPEN] [Tear here and pour]

[Three 4-inch antiseptic swabsticks impregnated with 10% W/V povidone iodine solution]

[0.75 Fl. oz (22.5 mL)]

Antiseptic Solution

For hospital and professional use only

MANUFACTURED BY

LERNAPHARM (LORIS) INC.

2323 HALPERN, VILLE ST-LAURENT

QUEBEC, CANADA H4S 1S3

70 mm 70 mm

7 mm

136mm |

7 mm

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Povidone lodine 10% w/v

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Directions: • Clean the area. • Apply product to the operative site prior to surgery. • Apply with friction for 30 seconds. • Do not blot or wipe away.

Other information:

• Store at room temperature between 59-86 °F (15-30°C) • 1% titratable iodine • latex free

Inactive ingredients: Citric Acid, Glycerol, Nonoxynol-9, Purified Water, Sodium Hydroxide, Sodium Phosphate Dibasic,

Questions or comments? Call 1-866-322-4634, weekdays between 8:00 am and 6:00 pm EST



Hold upright

Product # 119-01U

NDC: 68356-119-01



10% Povidone-lodine

TEAR OPEN

FAR ΩPEN

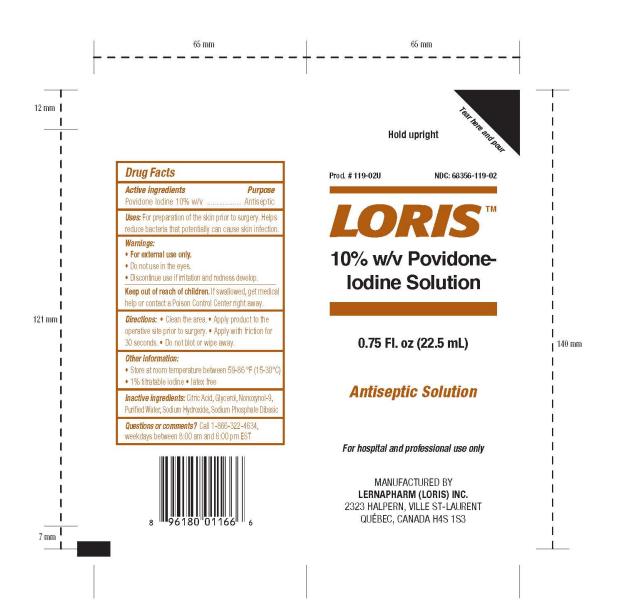
Three 4-inch antiseptic swabsticks impregnated with 10% W/V povidone iodine solution

Antiseptic Solution

For hospital and professional use only



MANUFACTURED BY LERNAPHARM (LORIS) INC. 2323 HALPERN, VILLE ST-LAURENT QUÉBEC, CANADA H4S 1S3 1_{150 mm}



LORIS POVIDONE-IODINE SOLUTION

POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)

SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)

povidone-iodine liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source	ce) NDC	C:68356-119
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingred	Basi	s of Strength	Strength	

Inactive Ingredients		
Ing	redient Name	Strength

IODINE

1 g in 100 mL

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68356- 119-02	22.5 mL in 1 POUCH; Type 0: Not a Combination Product	04/16/2013	
2	NDC:68356- 119-06	2.6 mL in 1 PACKET; Type 0: Not a Combination Product	07/14/2017	07/20/2022
3	NDC:68356- 119-07	2.6 mL in 1 PACKET; Type 0: Not a Combination Product	07/14/2017	07/20/2022
4	NDC:68356- 119-01	3 in 1 POUCH	04/16/2013	
4		2.5 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
5	NDC:68356- 119-03	1 in 1 POUCH	07/14/2017	07/20/2022
5		2.5 mL in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	04/13/2013	

Labeler - LernaPharm Loris Inc. (206940905)

Establishment				
Name	Address	ID/FEI	Business Operations	
LernaPharm Loris Inc.		206940905	manufacture(68356-119) , label(68356-119) , pack(68356-119)	

Revised: 10/2023 LernaPharm Loris Inc.