

LIGHTS POVIDONE IODINE SOLUTION- povidone-iodine solution
Lights Medical Manufacture Co., Ltd.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredient: Povidone-Iodine USP (10%)

Purpose: Antiseptic

Use: Antiseptic skin preparation

Warnings:

Do not use if allergic to iodine

For external use only

Do not use in eyes

Avoid "pooling" beneath patients. Prolonged exposure to wet solution may cause skin irritation

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

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

Apply locally as need

Other information

- 1% available iodine
- latex free
- for hospital or professional use only

Inactive Ingredient

Disodium hydrogen phosphate, citric acid, water



POVIDONE-IODINE SOLUTION

REF P-04-10

NDC:

4 Fl. Oz. (118 ml)

Drug Facts

Active ingredient	Purpose
Povidone-iodine USP 10%	Antiseptic
Use antiseptic skin preparation ▶	

Drug Facts, cont.

Warnings:

1. Do not use if allergic to iodine.
2. For external use only.
3. Ask a doctor before use if injuries are
 - deep or puncture wounds
 - serious burns
4. Stop use and ask a doctor if
 - redness, irritation, swelling or pain persists or increases
 - infection occurs
5. Do not use in eyes.
6. Avoid "pooling" beneath patient. Prolonged exposure to wet solution may cause skin irritation.
7. 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 need

Other information:

- 1% available iodine
- latex free
- for hospital or professional use only

Inactive ingredients:

disodium hydrogen phosphate, citric acid, purified water

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Made in China

LIGHTS POVIDONE IODINE SOLUTION

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61333-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	1.18 g in 118 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61333-201-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/04/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	02/22/2014	

Labeler - Lights Medical Manufacture Co., Ltd. (529128649)

Registrant - Lights Medical Manufacture Co., Ltd. (529128649)

Establishment

Name	Address	ID/FEI	Business Operations
Lights Medical Manufacture Co., Ltd.		529128649	manufacture(61333-201)

Revised: 1/2023

Lights Medical Manufacture Co., Ltd.