

POVIDONE IODINE- povidone iodine swab
Jianerkang Medical Co., Ltd

POVIDONE IODINE PREP SWABSTICK

Active Ingredients

Povidone Iodine USP 10% W/V (equivalent to 1% titratable iodine)

Purpose

Antiseptic

Uses

- Health-care antiseptic for preparation of the skin prior to surgery.
- First aid antiseptic to help prevent the risk of skin infection in minor cuts, scrapes, and burns.

Warnings

For external use only.

- Do not use in the eyes
- use on individuals who are allergic or sensitive to iodine
- apply over large areas of the body use as a first aid antiseptic longer than 1 week unless directed by a doctor.
- if irritation and redness develop. Consult a doctor in case of deep or puncture wounds animal bites serious burns. **Discontinue use**

Stop use and consult a doctor

if the condition persists or gets worse.

Keep out of reach of children

If swallowed, get medical help or contact Poison Control Center right away

Directions

For preparation of the skin prior to surgery

For use as a first aid antiseptic

- clean the affected area
- remove swab by stick
- apply to the operative site prior to surgery. **F**

- clean the affected area
- apply a small amount of this product on the area 1-3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first.

Other information

store at room temperature: 15°–30°C(59°-86°F)

Inactive Ingredients

citric acid, distilled water, sodium hydroxide, glycerin nonylphenol ethoxylate

Package Label

Drug Facts	Purpose
Active ingredient Povidone Iodine USP 10% WV (equivalent to 1% Itrazable Iodine)	Antiseptic
Use	• Health-care antiseptic for preparation of the skin prior to surgery • First aid antiseptic to help prevent the risk of skin infection in minor cuts, scrapes, and burns.
Warnings	• For external use only. Do not • use in the eyes • use on individuals who are allergic or sensitive to iodine • apply over large areas of the body • use as a first aid antiseptic longer than 1 week unless directed by a doctor. Discontinue use if irritation and redness develop. Consult a doctor in case of • deep or puncture wounds • animal bites • serious burns. Stop use and consult a doctor if the condition persists or gets worse. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions	• For preparation of the skin prior to surgery • clean the affected area • remove swab by stick • apply to the operative site prior to surgery. For use as a first aid antiseptic • clean the affected area • apply a small amount of this product on the area 1-3 times daily • may be covered with a sterile bandage • if bandaged, let dry first.
Other information	store at room temperature: 15°–30°C(59°-86°F)
Inactive ingredients	citric acid, distilled water, sodium hydroxide, glycerin nonylphenol ethoxylate

POVIDONE IODINE			
povidone iodine swab			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:34645-1043

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:34645-1043-1	1 in 1 POUCH	06/11/2015	
1		21 mL in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/11/2015	

Labeler - Jianerkang Medical Co., Ltd (530968767)

Establishment

Name	Address	ID/FEI	Business Operations
Jianerkang Medical Co., Ltd		530968767	manufacture(34645-1043)

Revised: 10/2023

Jianerkang Medical Co., Ltd