POVIDONE IODINE PREP- povidone-iodine solution
Jianerkang Medical 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.

Povidone Iodine Prep Swabstick

Drug Facts

Active ingredient

Povidone Iodine USP,7.5% W/V (equivalent to 0.75% titratable iodine)

Purpose

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

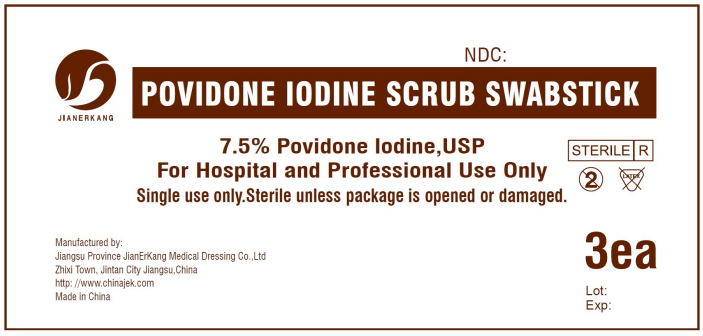
store at room temperature: 15°□30°C(59°-86°F)

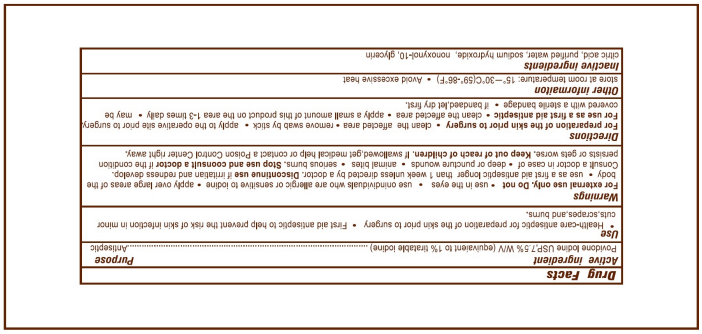
- Avoid excessive heat

Inactive ingredients

citric acid, purified water, sodium hydroxide, Nonoxynol-10, glycerin

Package Labeling:





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POVIDONE IODINE PREP

povidone-iodine solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:34645-5501
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	7.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
NONOXYNOL-10 (UNII: K7O76887AP)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:34645-5501-0	10 in 1 CARTON	02/03/2017	
1		25 in 1 BOX		
1		0.045 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/30/2017	

Labeler - Jianerkang Medical Co., Ltd (530968767)

Establishment

Name	Address	ID/FEI	Business Operations
Jianerkang Medical Co., Ltd		530968767	manufacture(34645-5501)

Revised: 3/2021 Jianerkang Medical Co., Ltd