POVIDONE IODINE PREP- povidone-iodine solution Jianerkang Medical Co., Ltd

Povidone Iodine Prep Swabstick

Drug Facts

Active ingredient

Povidone lodine USP, 10% 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

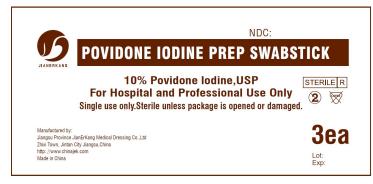
store at room temperature: 15° 30°C(59°-86°F)

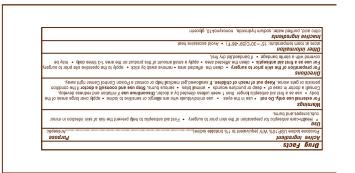
• Avoid excessive heat

Inactive ingredients

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

Package Labeling:





490c

POVIDONE IODINE PREP

povidone-iodine solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:34645-5504	
Route of Administration	TOPICAL			

ı	Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength	Strength		
ı	POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 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- 5504-0	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 Drug	M003	01/30/2017		

Labeler - Jianerkang Medical Co., Ltd (530968767)

Establishment					
Name	Address	ID/FEI	Business Operations		
Jianerkang Medical Co., Ltd		530968767	manufacture(34645-5504)		

Revised: 10/2023 Jianerkang Medical Co., Ltd