POVIDONE-IODINE PREP PAD- povidone-iodine swab
Foshan Flying Medical Products 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 PAD

Active ingredient

Povidone Iodine USP, 10% w/v (equivalent to 1% titratable iodine)

Purpose

Antiseptic

CAUTION: Keep out of reach of children

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

Indications and usage section

First aid to help prevent infection in minor cuts, scrapes, and burns

WARNINGS

For external use only. Flammable, keep away from fire or flame.

Do notuse

in the eyes or apply over large areas of the body.

on individuals who are allergic or sensitive to iodine.

Stop use

If irritation, redness or other symptoms develop.

Ask a doctor

If condition persists or gets worse or in case of deep or puncture wounds, animal bites, serious burns.

Directions

Apply product on the area 1-3 times daily and discard.

INACTIVE INGREDIENT

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

DRUG FACTS

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(equivalent to 1% titratable iodine)

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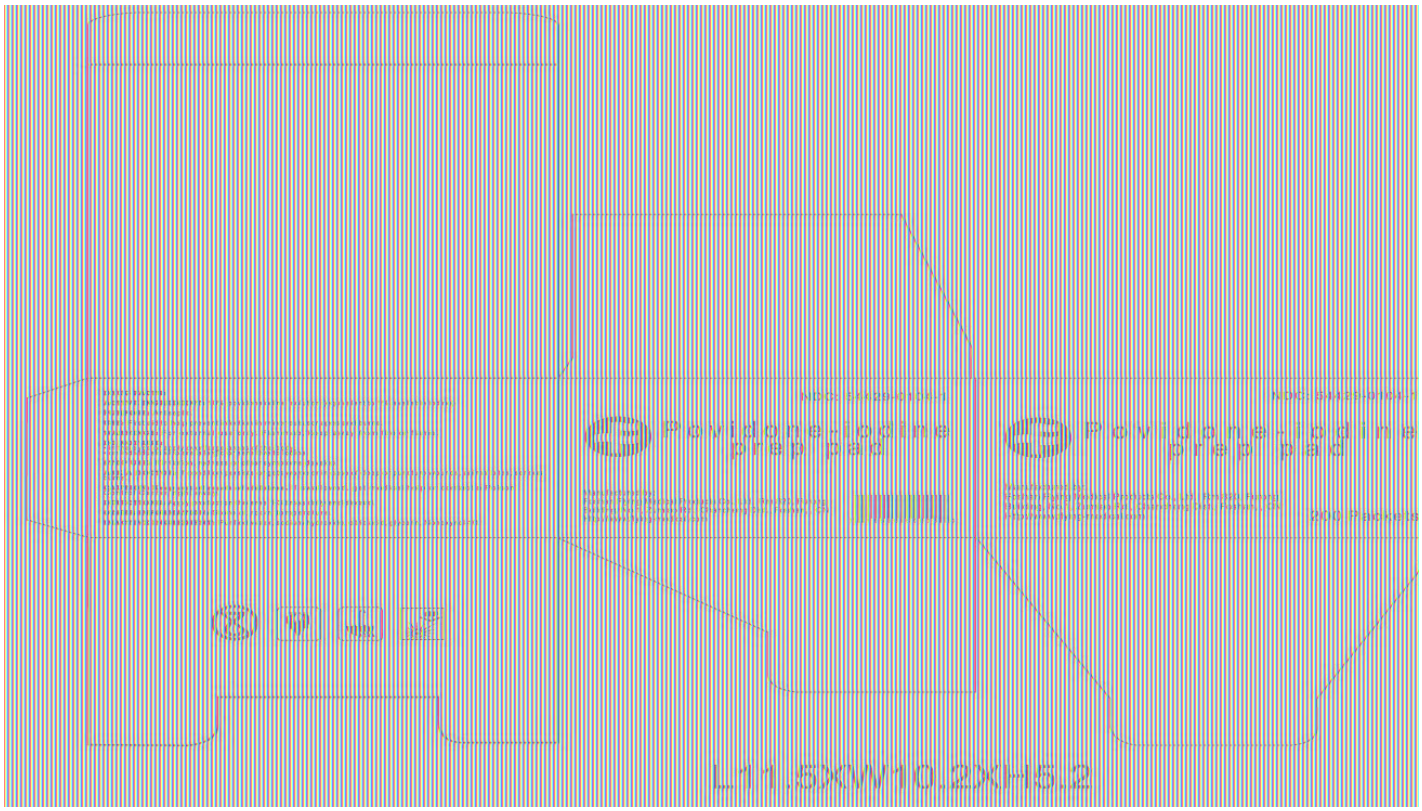
Directions

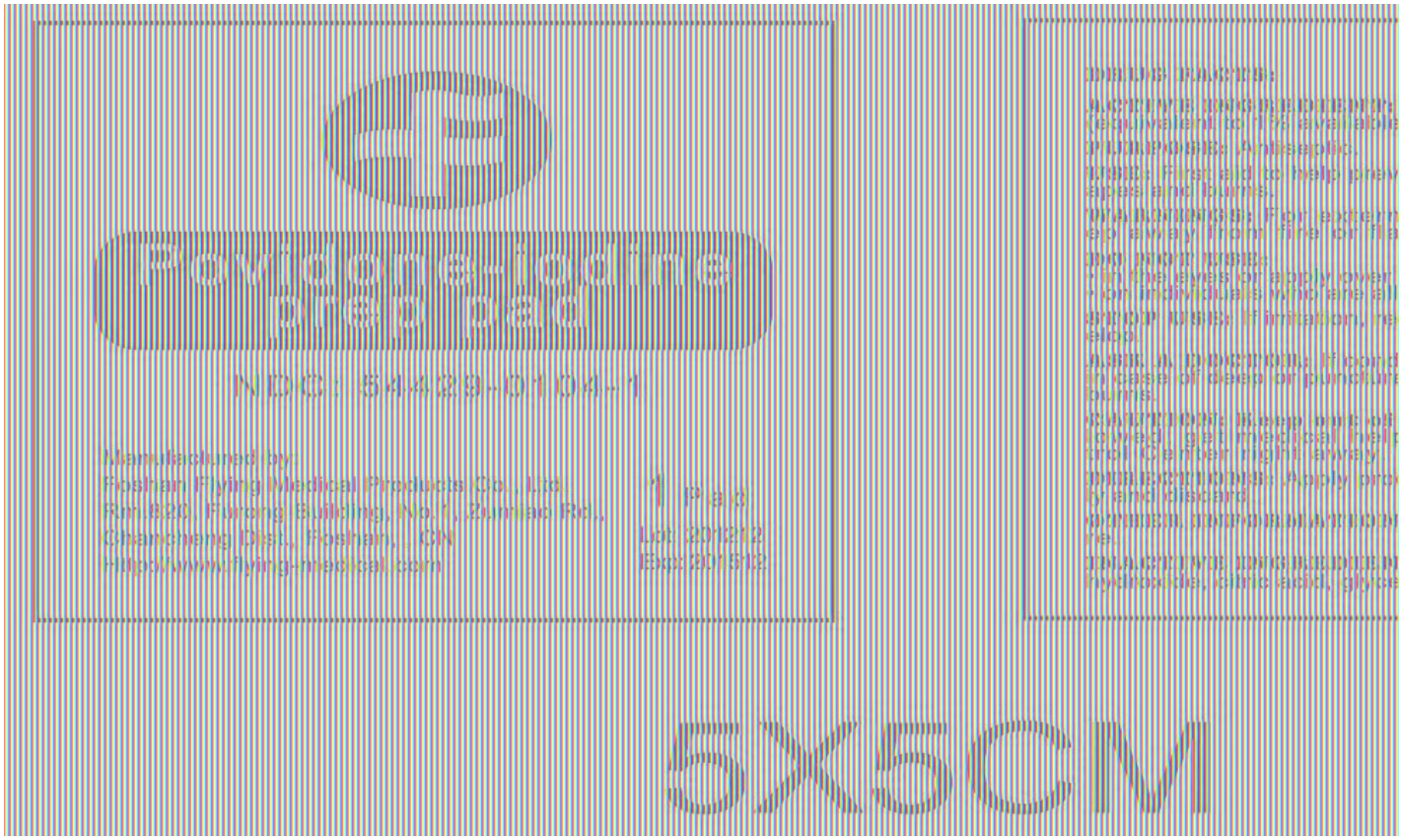
Apply product on the area 1-3 times daily and discard.

Other information: Store at room temperature.

Inactive ingredients

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





POVIDONE-IODINE PREP PAD

povidone-iodine swab

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54429-0104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	9.43 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54429-0104-1	9.43 g in 1 POUCH; Type 0: Not a Combination Product	01/15/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/15/2013	

Labeler - Foshan Flying Medical Products Co., Ltd. (527021584)

Registrant - Foshan Flying Medical Products Co., Ltd. (527021584)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Flying Medical Products Co., Ltd.		527021584	manufacture(54429-0104)

Revised: 10/2018 Foshan Flying Medical Products Co., Ltd.