SELECT BRAND POVIDONE IODINE- povidone iodine 10% liquid
Select Brand Distributors

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.

Select Brand Povidone Iodine

Drug Facts

Active Ingredient

Povidone-Iodine 10%

(Equivalent to 1% titrable iodine)

Purpose

Antiseptic

Use

First aid antiseptic to prevent infection in minor cuts and burns.

Warnings

For External Use Only

Ask a doctor before use if you have

- deep punture wounds
- animal bites
- serious burns

Stop use and consult a doctor if

- the condition persists or gets worse
- irritation and redness develop and persits for more than 72 hours

When using this product do not

- use in eyes
- use on individuals who are allergic or sensitive to iodine or use for longer than 1 week unless directed by a doctor
- apply over large areas of the body

Keep out of reach of children.

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions

For preparation of the skin prior to surgery: Apply to the operative site prior to surgery.

As a first aid antiseptic: Clean the affected area. Apply a small amount on the area 1 to 3 times daily. May be covered with sterile bandage. If badaged, let it dry first.

Other information

store at room temperature, 20-25C (68-77F)

Inactive Ingredients

Citric Acid, Disodium Phosphate, Glycerin, nonoxynol-9. Sodium Hydroxide and Purified Water.

Principal Display Panel

Label 8 fl oz

SELECT BRAND POVIDONE IODINE

povidone iodine 10% liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:15127-052
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	100 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:15127-052-55	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/12/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/01/2008	

Labeler - Select Brand Distributors (012578514)

Registrant - Humco Holding Group, Inc. (825672884)

Establishment

Name	Address	ID/FEI	Business Operations
Humco Holding Group, Inc.		825672884	manufacture(15127-052) , analysis(15127-052) , pack(15127-052) , label(15127-052)

Revised: 12/2017 Select Brand Distributors