POVIDONE IODINE- povidone iodine 10% ointment
Trifecta Pharmaceuticals USA LLC

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.

Globe Povidone Iodine USP 10%

Active Ingredient

Povidone Iodine USP 10%

w/w (available iodine 1%)

Purpose

First Aid Antiseptic

Uses

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

Warnings

For external Use Only

Do not use
- in eyes
- over large areas of the body
- if you are allergic to any of the ingredients

Directions
- Clean the affected area
- apply a small amount of this product (equal to the surface area of a fingertip) to the area 1 to 3 times daily.
- may be covered with a sterile bandage

Ask Doctor before use if you have
- deep or puncture wounds
- animal bites
- serious burns

Inactive Ingredients

Polyethylene glycol 400, Polyethylene glycol 4000

Questions?

Call 1-888-296-9067

Stop Use and Ask a doctor if

- The condition persists or gets worse
- you need to use this product for more than 1 week

Storage Information

- Store at controlled room temperature 20º to 25ºC (68ºF to 77ºF).
- close cap tightly after use.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center immediately (1-800-222-1222) right away.

Questions

1-888-296-9067

Other Information

Distributed By:

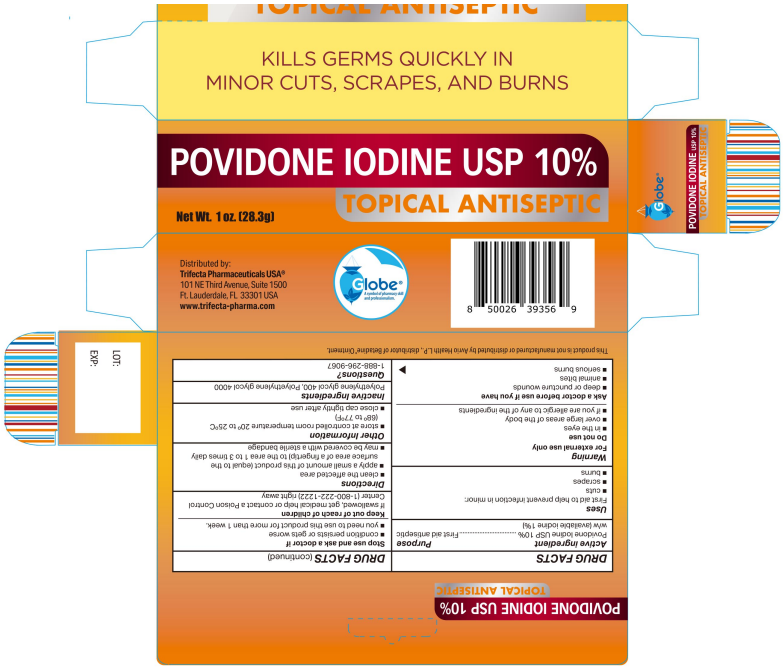
Trifecta Pharmaceuticals USA®

101 NE Third Ave. Ste 1500

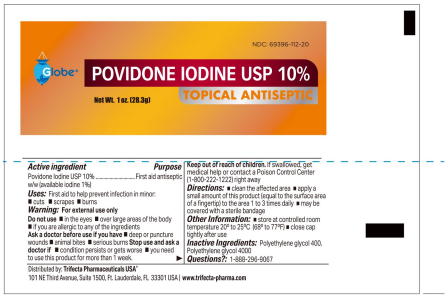
Ft. Lauderdale, FL. 33301 USA

www.trifecta-pharma.com

OUTSIDE BOX



INNER TUBE



POVIDONE IODINE

povidone iodine 10% ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69396-112
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 g

Inactive Ingredients	
Ingredient Name	**Strength**
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-112-20	1 in 1 BOX	12/23/2022	
1		28.3 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/23/2022	

Labeler - Trifecta Pharmaceuticals USA LLC (079424163)

Registrant - Trifecta Pharmaceuticals USA (079424163)

Revised: 1/2023 Trifecta Pharmaceuticals USA LLC