

FIRST AID ANTISEPTIC- povidone-iodine solution

Topco Associates 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.

Povidone-Iodine

050

Active ingredient

Povidone-iodine, 10%
(equivalent to 1% available iodine)

Purpose

First aid antiseptic

use

first aid to help prevent the risk of infection in minor cuts, scrapes and burns

warnings

For external use only

ask a doctor before use if you have

- deep or puncture wounds
- animals bites
- serious burns

When using this product

- do not get into eyes or apply over large areas of the body.
- do not use longer than 1 week unless directed by a doctor

stop use and ask a doctor if

- 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

- clean the affected area
- apply a small amount of this product on the area 1 to 3 times daily
- may be covered with a sterile bandage.
- if bandaged, let dry first.

Other information

- Store between 15°-30°C (59°-86°F)

inactive ingredients

C12-13 Pareth-9, citric acid, disodium phosphate, glycerin, sodium hydroxide, water

*This product is not manufactured or distributed by Purdue Products LP., distributor of Betadine Solution Povidone-Iodine 10%

DISTRIBUTED BY

TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

TOPCO VIJ613

QUESTIONS? 1-888-423-0139

topcare@topco.com

050.002/050AE

Principal display panel

TopCare

Povidone-Iodine Solution, 10%

FIRST AID ANTISEPTIC

- Kills germs in minor burns, cuts and scrapes

Compare to Betadine Solution active ingredient*

8 FL OZ (237 mL)

TopCare®

Povidone- Iodine Solution, 10%

FIRST AID ANTISEPTIC

- **Kills germs in minor burns,
cuts and scrapes**



**Compare to
Betadine® Solution
active ingredient*

8 FL OZ (237 mL)

FIRST AID ANTISEPTIC

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
C12-13 PARETH-9 (UNII: 9BXD858P37)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-011-34	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/2004	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/29/2004	

Labeler - Topco Associates LLC (006935977)

Registrant - Vi Jon (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi Jon		790752542	manufacture(36800-011)