POVIDONE IODINE - povidone-iodine solution
Triad Group

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.

DRUG FACTS

ACTIVE INGREDIENT

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

PURPOSE

Antiseptic

USE

First aid antiseptic to help prevent the risk of 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

Discontinue use and ask a doctor

- if condition persists or gets worse
- for use longer than 1 week

Ask a doctor in case of

- deep or puncture wounds
- animal bites
- serious burns

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 to 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)

INACTIVE INGREDIENTS
citric acid, glycerin, Makon 8, purified water, sodium hydroxide

PACKAGE INFORMATION

MEDIC®

NDC 50730-8230-1

**COMPARE TO THE ACTIVE INGREDIENT IN BETADINE®*
10% Topical Solution
Povidone
Iodine

For External Use Only

Helps prevent the risk of infection in minor cuts, scrapes and burns

8 FL OZ (236 mL)

Distributed by Winn-Dixie Stores, Inc.
Jacksonville, FL 32254

Quality Guaranteed
1-866-WINN-DIXIE
www.winn-dixie.com

*This product is not manufactured or distributed by Purdue Frederick, owner of the registered trademark, Betadine®.

POVIDONE IODINE

povidone-iodine solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50730-8230
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
povidone-iodine (UNII: 85H0HZU99M) (povidone-iodine - UNII:85H0HZU99M)	povidone-iodine	0.10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
citric acid monohydrate (UNII: 2968PHW8QP)	
glycerin (UNII: PDC6A3C0OX)	

sodium hydroxide (UNII: 55X04QC32I)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50730-8230-1	236 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/06/2007	

Labeler - Triad Group (050259597)

Revised: 2/2010 Triad Group