

POVIDONE IODINE - povidone-iodine solution

Kmart Corporation

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 USP, 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, nonoxynol-8, purified water, sodium hydroxide

LABEL INFORMATION

Compare to active ingredient of **Betadine® Solution***

NDC 49738-050-34

AMERICAN FARE

POVIDONE- IODINE SOLUTION

- First Aid Antiseptic
- Kills germs in minor burns, cuts and scrapes

8 fl. oz. (236 mL)

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

If you are not completely satisfied with this or any *American Fare* product, please call 1-800-842-7886.

Distributed by:

Kmart Corporation

Hoffman Estates, IL 60179

Made in USA

Compare to active ingredient of **Betadine® Solution***

NDC 49738-050-34



POVIDONE- IODINE SOLUTION

LOT

EXP

no print area
magenta does not print

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Drug Facts

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Drug Facts (continued)

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Rev. A0806



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Hoffman Estates, IL 60179
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VENDOR: PLEASE
PLACE UPC
0-72000-26698-4

POVIDONE IODINE

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49738-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
povidone-iodine (UNII: 85H0HZU99M) (povidone-iodine - UNII:85H0HZU99M)	povidone-iodine	.10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
citric acid monohydrate (UNII: 2968PHW8QP)	
glycerin (UNII: PDC6A3C0OX)	
sodium hydroxide (UNII: 55X04QC32I)	

water (UNII: 059QF0K00R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49738-050-34	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	09/13/2006	

Labeler - Kmart Corporation (008965873)

Revised: 4/2010

Kmart Corporation