

POVIDONE IODINE - povidone iodine ointment

CVS Pharmacy

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

Section from Tube Label Follows:

Active Ingredient	Purpose
Povidone iodine 10% (available iodine 1%)	First aid antiseptic

Section from Carton Label Follows:

Active ingredient	Purpose
Povidone iodine 1% (available iodine 1%)	First aid antiseptic

Section from Tube Label Follows:

Active Ingredient	Purpose
Povidone iodine 10% (available iodine 1%)	First aid antiseptic

Uses first aid to help prevent infection in

- minor cuts
- scrapes
- burns

Section from Carton Label Follows:

Active ingredient	Purpose
Povidone iodine 1% (available iodine 1%)	First aid antiseptic

Uses

first aid to help prevent infection in - minor cuts - scrapes - burns

Section from **Warnings** portion of tube label follows:

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Section from **Warnings** section of Carton label follows:

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Section from Directions portion of tube label follows:

Directions - clean the affected area and dry thoroughly
- apply a small amount of this product on the area 1 to 3 times daily - May be covered with a sterile bandage

Section from Directions portion of carton label follows:

Directions

- clean the affected area and dry thoroughly
- apply a small amount of this product on the area 1 to 3 times daily
- May be covered with a sterile bandage

From **Warnings** Section of Tube Label:

Warnings For external use only. Do not use - In the eyes
- over large areas of the body - longer than 1 week unless directed by a doctor. **Ask a doctor before use** - in case of deep or puncture wounds, animal bites, or serious burns. **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.

From **Warnings** Section of Carton Label:

Warnings

For external use only.

Do not use - In the eyes - over large areas of the body
- longer than 1 week unless directed by a doctor.

Ask a doctor before use - in case of deep or puncture wounds, animal bites, or serious burns.

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.

Section from Directions portion of tube label follows:

Directions - clean the affected area and dry thoroughly
- apply a small amount of this product on the area 1 to 3 times daily - May be covered with a sterile bandage

Section from Directions portion of carton label follows:

Directions

- clean the affected area and dry thoroughly
- apply a small amount of this product on the area 1 to 3 times daily
- May be covered with a sterile bandage

From Inactive Ingredients section of Tube Label:

Inactive Ingredients PEG-75, PEG-8, purified water

From Inactive Ingredients section of Carton Label:

Inactive Ingredients PEG-75, PEG-8, purified water

Carton



FIRST AID ANTISEPTIC

MAXIMUM STRENGTH POVIDONE IODINE OINTMENT USP, 10%

Kills germs promptly in:
• Minor burns • Cuts • Scrapes



Compare to the active ingredient in Betadine® Ointment*

MAXIMUM STRENGTH POVIDONE IODINE OINTMENT USP, 10% FIRST AID ANTISEPTIC



MAXIMUM STRENGTH
POVIDONE IODINE OINTMENT
USP, 10%
FIRST AID ANTISEPTIC

NET WT 1 OZ (28.4 g)



Compare to the active ingredient in Betadine® Ointment*



MAXIMUM STRENGTH POVIDONE IODINE OINTMENT USP, 10% FIRST AID ANTISEPTIC

Available iodine 1%

NET WT 1 OZ (28.4 g)

BX023CVS10Z-2

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This product is not manufactured or distributed by Purdue Pharma L.P., the owner of the trademark Betadine®

Drug Facts
Active ingredient Povidone iodine 10% (available iodine 1%).....First aid antiseptic
Uses First aid to help prevent infection in • minor cuts • scrapes • burns
Warnings For external use only Do not use • in the eyes • over large areas of the body • longer than 1 week unless directed by a doctor Ask a doctor before use • in case of deep or puncture wounds, animal bites, or serious burns 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 and dry thoroughly • apply a small amount of this product on the area 1 to 3 times daily • may be covered with a sterile bandage Other information • To open: unscrew cap, pull tab to remove foil seal • store at room temperature • protect from freezing • see carton or tube crimp for lot number and expiration date
Inactive ingredients PEG-75, PEG-8, purified water

POVIDONE IODINE

povione iodine ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-085
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	POVIDONE-IODINE	1 g in 10 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)	2.5 g in 10 g
WATER (UNII: 059QF0K00R)	0.5 g in 10 g
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	6 g in 10 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-085-99	1 in 1 CARTON		
1		28.4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	07/30/2008	

Labeler - CVS Pharmacy (062312574)

Registrant - Pharma Pac, LLC (140807475)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture