MAJOR POVIDONE IODINE- povidone-iodine ointment Major Pharmaceuticals

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 USP10% w/w (available iodine 1%)

Purpose

Antiseptic-germicidal

Uses

for the treatment of:

- minor wounds
- infections
- kills bacteria promptly

Warnings

For external use only.

Do not use

- over large areas of the body
- if you are allergic to any of the ingredients
- longer than 1 week unless directed by a doctor

When using this product

• Avoid contact with eyes.

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

• redness, irritation or swelling occurs or pain persists

Keep this and all drugs out of the reach of children.

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions

- apply directly to affected area
- may be bandaged

Other information

- Store at controlled room temperature 15°-30°C (59°-86°F).
- Close cap tightly after use.
- For control no. and expiration date, see carton and/or crimp of tube.
- Will not stain natural fabrics.
- Protect from freezing.

Inactive ingredients

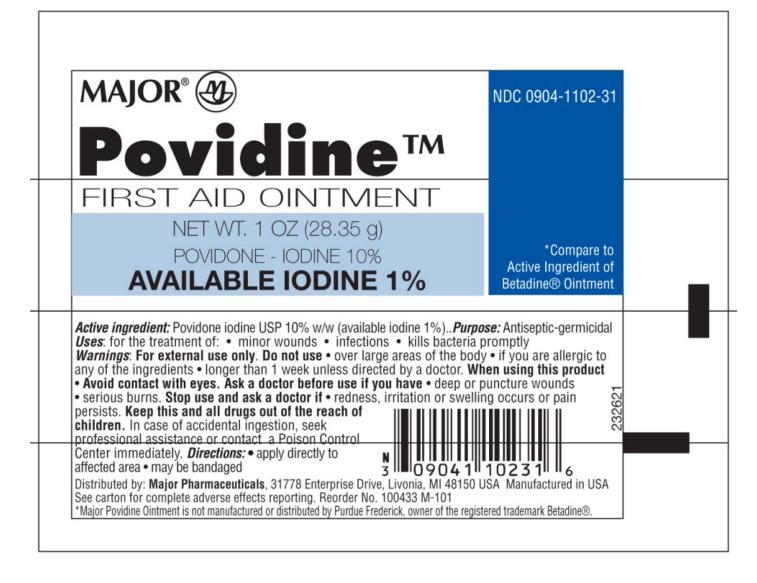
glycerin, PEG-6, PEG-32, propylene glycol

Questions?

Adverse Drug Event call (800)616-2471 Dist. By MAJOR PHARMACEUTICALS 31778 Enterprise Drive, Livonia, Ml 48150 USA Re-Oder No. 100433 M-101

Principal Display Panel – 1 oz. Tube

Major[®] NDC 0904-1102-31 Povidine[™] FIRST AID OINTMENT NET WT. 1 OZ (28.35 g) *Compare to POVIDINE – IODINE 10% Active Ingredient of AVAILABLE IODINE 1% Betadine® Ointment



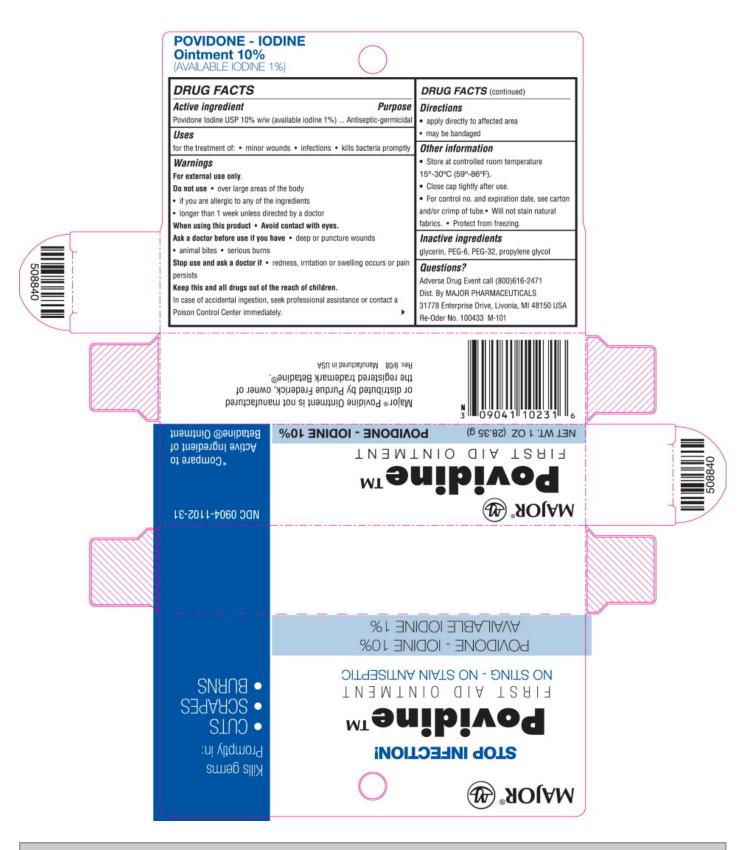
Principal Display Panel – 1 oz. Carton

Major[®] NDC 0904-1102-31

Povidine[™] *Compare to

FIRST AID OINTMENT Active Ingredient of

NET WT. 1OZ (28.35 g) POVIDINE - IODINE 10% Betadine® Ointment



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povidone-iodine ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-1102
Route of Administration	TOPICAL		

40	ctive Ingredien	Active Molety				
		Ingredient Name		Basis of Stre	ngth	Strength
PO	VIDO NE-IO DINE (UNII: 85H0 HZU99M) (IODINE - UNII:9679TC07X4)		IODINE		100 mg in 1 g
In	active Ingredie	nts				
		Ingredient Name				Strength
GL	L YCERIN (UNII: PDC					
РО	LYETHYLENE GL	YCOL 300 (UNII: 5655G9Y8AQ)				
		YCOL 1500 (UNII: 1212Z7S33A)				
PO	LYETHYLENE GL	YCOL 1500 (UNII: 1212Z7S33A) L (UNII: 6DC9Q167V3)				
PO PR	LYETHYLENE GL					
PO PR Pa	DLYETHYLENE GL OPYLENE GLYCO		Market	ing Start Date	Mark	eting End Dat
PO PR Pa	DLYETHYLENE GL COPYLENE GLYCO Ackaging	L (UNII: 6DC9Q167V3) Package Description	Market 08/14/20	-	Mark	eting End Dat
PO PR Pa #	OLYETHYLENE GL OPYLENE GLYCO Ackaging Item Code	L (UNII: 6DC9Q167V3) Package Description		-	Mark	eting End Dat
PO PR Pa	OLYETHYLENE GL OPYLENE GLYCO Ackaging Item Code	L (UNII: 6DC9Q167V3) Package Description 1 in 1 CARTON		-	Mark	eting End Dat
PO PR # 1 1	DLYETHYLENE GL COPYLENE GLYCO Ackaging Item Code NDC:0904-1102-31	L (UNII: 6DC9Q167V3) Package Description 1 in 1 CARTON 28.35 g in 1 TUBE; Type 0: Not a Combination Product		-	Mark	eting End Da
PO PR # 1 1	OLYETHYLENE GL COPYLENE GLYCO Ackaging Item Code NDC:0904-1102-31	L (UNII: 6DC9Q167V3) Package Description 1 in 1 CARTON 28.35 g in 1 TUBE; Type 0: Not a Combination Product Drmation		-		
PO PR # 1 1	DLYETHYLENE GL COPYLENE GLYCO Ackaging Item Code NDC:0904-1102-31	L (UNII: 6DC9Q167V3) Package Description 1 in 1 CARTON 28.35 g in 1 TUBE; Type 0: Not a Combination Product Drmation	08/14/20	-		eting End Dat

Labeler - Major Pharmaceuticals (191427277)

Revised: 1/2021

Major Pharmaceuticals