

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, MI 48150 USA

Re-Order 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

MAJOR® 

NDC 0904-1102-31

Povidine™

FIRST AID OINTMENT

NET WT. 1 OZ (28.35 g)

POVIDONE - IODINE 10%

AVAILABLE IODINE 1%

*Compare to
Active Ingredient of
Betadine® Ointment

Active ingredient: Povidone iodine USP 10% 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
• 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



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Distributed by: Major Pharmaceuticals, 31778 Enterprise Drive, Livonia, MI 48150 USA Manufactured in USA
See carton for complete adverse effects reporting. Reorder No. 100433 M-101
*Major Povidine Ointment is not manufactured or distributed by Purdue Frederick, owner of the registered trademark Betadine®.

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) **POVIDONE - IODINE 10%** Betadine® Ointment

POVIDONE - IODINE
Ointment 10%
(AVAILABLE IODINE 1%)

DRUG FACTS

Active ingredient Purpose
Povidone Iodine USP 10% w/w (available iodine 1%) ... Antiseptic-germicidal

Uses
for the treatment of: • minor wounds • infections • kills bacteria promptly

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When using this product • Avoid contact with eyes.
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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.

DRUG FACTS (continued)

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?
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Dist. By MAJOR PHARMACEUTICALS
31778 Enterprise Drive, Livonia, MI 48150 USA
Re-Order No. 100433 M-101



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Rev. 9/08 Manufactured in USA



NET WT. 1 OZ (28.35 g) POVIDONE - IODINE 10% Compare to Active Ingredient of Betadine® Ointment

POVIDONE - IODINE 10%
FIRST AID OINTMENT
Povidone™
MAJOR®



NDC 0904-1102-31

POVIDONE - IODINE 10%
AVAILABLE IODINE 1%

STOP INFECTION!
Povidone™
FIRST AID OINTMENT
NO STING - NO STAIN ANTISEPTIC
MAJOR®

Kills germs
Promptly in:
• CUTS
• SCRAPES
• BURNS

MAJOR POVIDONE IODINE

povidone-iodine ointment

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-1102-31	1 in 1 CARTON	08/14/2006	
1		28.35 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	08/14/2006	

Labeler - Major Pharmaceuticals (191427277)

Revised: 1/2021

Major Pharmaceuticals