#### 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.

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## 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**

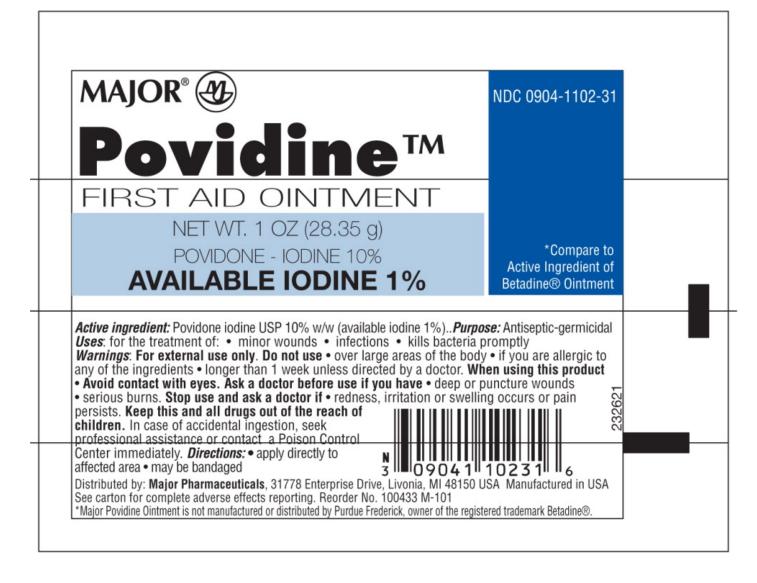
glycerin, PEG-6, PEG-32, propylene glycol

#### 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<sup>®</sup> NDC 0904-1102-31 Povidine<sup>™</sup> FIRST AID OINTMENT NET WT. 1 OZ (28.35 g) \*Compare to POVIDINE – IODINE 10% Active Ingredient of AVAILABLE IODINE 1% Betadine® Ointment



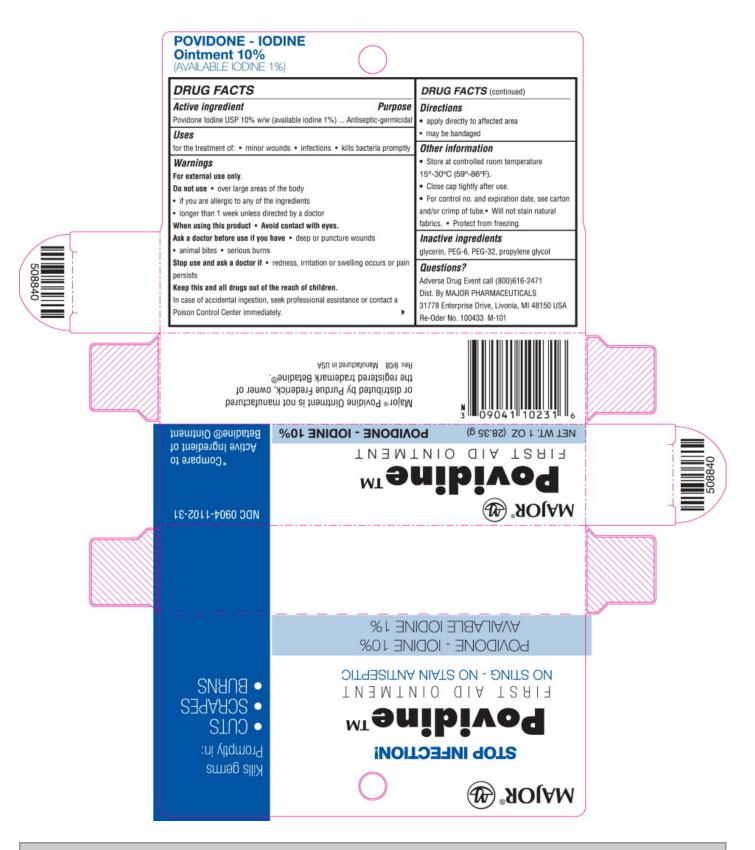
# Principal Display Panel – 1 oz. Carton

**Major**<sup>®</sup> NDC 0904-1102-31

**Povidine**<sup>™</sup> \*Compare to

FIRST AID OINTMENT Active Ingredient of

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



|  | MAJO | R PO' | VIDONE | IODINE |
|--|------|-------|--------|--------|
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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 <b>YCERIN</b> (UNII: PDC  |  |                           |                |      |               |
| РО                   | LYETHYLENE GL   | YCOL 300 (UNII: 5655G9Y8AQ)  |                           |                |      |               |
|                      |   |  |                           |                |      |               |
|                      |   | YCOL 1500 (UNII: 1212Z7S33A)   |                           |                |      |               |
| PO                   | LYETHYLENE GL   | YCOL 1500 (UNII: 1212Z7S33A)<br>L (UNII: 6DC9Q167V3)   |                           |                |      |               |
| PO<br>PR             | LYETHYLENE GL   |  |                           |                |      |               |
| PO<br>PR<br>Pa       | DLYETHYLENE GL<br>OPYLENE GLYCO   |  | Market                    | ing Start Date | Mark | eting End Dat |
| PO<br>PR<br>Pa       | DLYETHYLENE GL<br>COPYLENE GLYCO<br>Ackaging                                  | L (UNII: 6DC9Q167V3)<br>Package Description  | <b>Market</b><br>08/14/20 | -              | Mark | eting End Dat |
| PO<br>PR<br>Pa<br>#  | OLYETHYLENE GL<br>OPYLENE GLYCO<br>Ackaging<br>Item Code                      | L (UNII: 6DC9Q167V3)<br>Package Description  |                           | -              | Mark | eting End Dat |
| PO<br>PR<br>Pa       | OLYETHYLENE GL<br>OPYLENE GLYCO<br>Ackaging<br>Item Code                      | L (UNII: 6DC9Q167V3) Package Description 1 in 1 CARTON   |                           | -              | Mark | eting End Dat |
| PO<br>PR<br>#<br>1 1 | DLYETHYLENE GL<br>COPYLENE GLYCO<br>Ackaging<br>Item Code<br>NDC:0904-1102-31 | L (UNII: 6DC9Q167V3)<br>Package Description<br>1 in 1 CARTON<br>28.35 g in 1 TUBE; Type 0: Not a Combination Product             |                           | -              | Mark | eting End Da  |
| PO<br>PR<br>#<br>1 1 | OLYETHYLENE GL<br>COPYLENE GLYCO<br>Ackaging<br>Item Code<br>NDC:0904-1102-31 | L (UNII: 6DC9Q167V3)<br>Package Description<br>1 in 1 CARTON<br>28.35 g in 1 TUBE; Type 0: Not a Combination Product<br>Drmation |                           | -              |      |               |
| PO<br>PR<br>#<br>1 1 | DLYETHYLENE GL<br>COPYLENE GLYCO<br>Ackaging<br>Item Code<br>NDC:0904-1102-31 | L (UNII: 6DC9Q167V3)<br>Package Description<br>1 in 1 CARTON<br>28.35 g in 1 TUBE; Type 0: Not a Combination Product<br>Drmation | 08/14/20                  | -              |      | eting End Dat |

# Labeler - Major Pharmaceuticals (191427277)

Revised: 1/2021

Major Pharmaceuticals