POVIDONE IODINE- povidone iodine solution
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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Povidone Iodine Prep

Active ingredient

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Povidone Iodine 10% v/v</td>
<td>Antiseptic</td>
</tr>
</tbody>
</table>

Uses

- First aid antiseptic to help prevent infection in minor cuts, scrapes and burns.
- Healthcare antiseptic for preparation of the skin prior to surgery.
- Antiseptic cleanser for preparation of skin prior to an infection.

Warnings

- FOR EXTERNAL USE ONLY

Do not use

- As a first aid antiseptic for more than 1 week unless directed by a doctor.
- In the eyes.
- Over large areas of the body.
- On individuals who are allergic or sensitive to iodine.

Ask a doctor before use if you have

- Deep puncture wounds
- Animal bites
- Serious burns

Stop Use

- If irritation and redness develop
- If condition persists for more than 72 hours, consult a physician.

Keep Out Of Reach Of Children

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

Directions

As a first aid antiseptic

- clean affected area
apply a small amount of this product to the area 1 to 3 times daily
may be covered with a sterile bandage, if bandaged let dry.

For preoperative patient skin preparation

- clean area
- apply to operative site prior to surgery using the applicator

Inactive Ingredient
- citric acid
- glycerin
- sodium citrate
- tween 80
- disodium phosphate
- purified Water

For use as an
- first aid antiseptic
- pre-operative skin preparation

Principal Display Panel
### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)</td>
<td>IODINE</td>
<td>100 mg in 1 mL</td>
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</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tbody>
<tr>
<td>CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)</td>
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<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
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<tr>
<td>GLYCYRIN (UNII: PDC6A3C0OX)</td>
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<tr>
<td>SODIUM CITRATE (UNII: 1Q73Q2JULR)</td>
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<td>POLYSORBATE 80 (UNII: 6OZP39ZG8H)</td>
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<td>SODIUM PHOSPHATE (UNII: SE337SYV37)</td>
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### Packaging

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<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<td>1</td>
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<td>237 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>12/21/2011</td>
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### Marketing Information

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<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<td>OTC monograph final</td>
<td>part333C</td>
<td>12/21/2011</td>
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### Labeler

Major Pharmaceuticals (191427277)

Revised: 8/2019