POVIDONE IODINE - povione 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.

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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
# MAXIMUM STRENGTH

## Povidone Iodine Ointment

**USP, 10%**

**First Aid Antiseptic**

**Kills germs promptly in:**
- Minor burns
- Cuts
- Scrapes

**Available iodine 1%**

NET WT 1 OZ (28.4 g)

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**Ingredients:**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Povidone</td>
<td>55%</td>
</tr>
<tr>
<td>Iodine</td>
<td>10%</td>
</tr>
<tr>
<td>Water</td>
<td>35%</td>
</tr>
</tbody>
</table>

**Other Information:**

- **Directions:**
  - Use following directions for location and application.
  - Apply a small amount of the product on the wound 2 to 3 times daily.
  - Allow to dry before dressings are applied.

**Warnings:**

- **For external use only.**
- **Do not use over large areas of the body.**
- **Not for use in children.**

**Uses:**

- First aid antiseptic

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**Active Ingredient:**

Oxidized Iodine (available iodine 1.9%)
# POVIDONE IODINE
povione iodine ointment

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
<td>NDC:59779-085</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Route of Administration</th>
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<tbody>
<tr>
<td>TOPICAL</td>
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</table>

## 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>POVIDONE-IODINE</td>
<td>1 g in 10 g</td>
</tr>
</tbody>
</table>

## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)</td>
<td>2.5 g in 10 g</td>
</tr>
<tr>
<td>WATER (UNII: 059QF0K00R)</td>
<td>0.5 g in 10 g</td>
</tr>
<tr>
<td>POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)</td>
<td>6 g in 10 g</td>
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</table>

## Packaging

<table>
<thead>
<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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<tbody>
<tr>
<td>1</td>
<td>NDC:59779-085-99</td>
<td>1 in 1 CARTON</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>28.4 g in 1 TUBE</td>
<td></td>
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</table>

## Marketing Information

<table>
<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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<tbody>
<tr>
<td>OTC monograph not final</td>
<td>part333A</td>
<td>07/30/2008</td>
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## Labeler

- CVS Pharmacy (062312574)

## Registrant

- Pharma Pac, LLC (140807475)

## Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tbody>
<tr>
<td>Pharma Pac, LLC</td>
<td></td>
<td>140807475</td>
<td>manufacture</td>
</tr>
</tbody>
</table>

**Revised:** 2/2011