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 Ingredients
Povidone Iodine 10% w/v

Purpose
Antiseptic

Uses
For preparation of the skin prior to surgery. Helps reduce bacteria that potentially can cause skin infection.

Warnings
For External Use Only

- Do not use in the eyes.
- Discontinue use if irritation and redness develop.

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

Directions

- Clean the area.
- Apply product to the operative site prior to surgery.
- Apply with friction for 30 seconds.
- Do not blot or wipe away.

Other Information
Store at room temperature between 59-86°F (15-30°C). 1% titratable iodine. Latex free

Inactive Ingredients
Citric Acid, Glycerol, Nonoxynol-9, Purified Water, Sodium Hydroxide, Sodium Phosphate Dibasic

Questions or comments?
Call 1-866-322-4634, weekdays between 8:00 am and 6:00 pm EST

Principal Display Panel
Hold upright
Product # 119-XXU          NDC: 68356-119-XX
Loris Povidone-Iodine [Solution]
[TEAR OPEN] [Tear here and pour]
Antiseptic
STERILE Solution
[Applicator is sterile] Unless package is opened or damaged
For hospital and professional use only
MANUFACTURED BY
LERNAPHARM (LORIS) INC.
2323 HALPERN, VILLE ST-LAURENT
QUEBEC, CANADA H4S 1S3
**Drug Facts**

**Active Ingredients**
- Povidone-Iodine 10% w/v

**Proprietary Name:** Loris

**Route:** Topical

**Purpose:** Antiseptic

**Dosage:**
- For external use only.
- Apply a sufficient amount to cover the area being cleansed.

**Warnings:**
- Do not use on the eyes.
- Do not use in the mouth.
- Do not use in the ears.

**Precautions:**
- For external use only.
- Avoid contact with the eyes, nose, and mouth.
- Store at room temperature.

**Directions:**
- Apply a sufficient amount to cover the area being cleansed.

**Other Information:**
- Do not use in the mouth.
- Store at room temperature.

**Manufactured by:**
- Lernapharm (Loris) Inc.
- 2323 Haperial, Ville St-Laurent, Quebec, Canada H4S 1S3

---

**Drug Facts**

**Active Ingredients**
- Povidone-Iodine 10% w/v

**Proprietary Name:** Loris

**Route:** Topical

**Purpose:** Antiseptic

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**Warnings:**
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- Store at room temperature.

**Precautions:**
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- Avoid contact with the eyes, nose, and mouth.

**Directions:**
- Apply a sufficient amount to cover the area being cleansed.

**Other Information:**
- Do not use in the mouth.
- Store at room temperature.

**Manufactured by:**
- Lernapharm (Loris) Inc.
- 2323 Haperial, Ville St-Laurent, Quebec, Canada H4S 1S3
LORIS POVIDONE-IODINE SOLUTION

povidone-iodine liquid

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:68356-119</td>
</tr>
<tr>
<td>TOPICAL</td>
<td></td>
</tr>
</tbody>
</table>

Active Ingredient/Active Moiety
# 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>1 g in 100 mL</td>
</tr>
</tbody>
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## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anhydrous Citric Acid (UNII: XF417D3PSL)</td>
<td></td>
</tr>
<tr>
<td>Glycerin (UNII: PDC6A3COOX)</td>
<td></td>
</tr>
<tr>
<td>Nonoxynol-9 (UNII: 48Q180SHBT)</td>
<td></td>
</tr>
<tr>
<td>Water (UNII: 059QF0KOOR)</td>
<td></td>
</tr>
<tr>
<td>Sodium Hydroxide (UNII: 55X04QC32I)</td>
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</tr>
<tr>
<td>Sodium Phosphate, Dibasic (UNII: GR668LBA74)</td>
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</tbody>
</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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:68356-119-02</td>
<td>22.5 mL in 1 POUCH; Type 0: Not a Combination Product</td>
<td>04/16/2013</td>
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<tr>
<td>2</td>
<td>NDC:68356-119-06</td>
<td>2.6 mL in 1 PACKET; Type 0: Not a Combination Product</td>
<td>07/14/2017</td>
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<tr>
<td>3</td>
<td>NDC:68356-119-07</td>
<td>2.6 mL in 1 PACKET; Type 0: Not a Combination Product</td>
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<tr>
<td>4</td>
<td>NDC:68356-119-01</td>
<td>3 in 1 POUCH</td>
<td>04/16/2013</td>
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<tr>
<td>4</td>
<td></td>
<td>2.5 mL in 1 APPLICATOR; Type 0: Not a Combination Product</td>
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<tr>
<td>5</td>
<td>NDC:68356-119-03</td>
<td>1 in 1 POUCH</td>
<td>07/14/2017</td>
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<tr>
<td>5</td>
<td></td>
<td>2.5 mL in 1 APPLICATOR; Type 0: Not a Combination Product</td>
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## 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>part333E</td>
<td>04/16/2013</td>
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## Labeler

- **LernaPharm Loris Inc.** (206940905)

## 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>LernaPharm Loris Inc.</td>
<td>206940905</td>
<td>manufacture(68356-119), label(68356-119), pack(68356-119), sterilize(68356-119)</td>
<td></td>
</tr>
</tbody>
</table>

Revised: 7/2017