LORIS 10% POVIDONE-IODINE AND 70% ISOPROPYL ALCOHOL SOLUTION- povidone-
iode and isopropyl alcohol liquid
LernaPharm Loris Inc.

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 Ingredients
Povidone Iodine 10% w/v
Isopropyl Alcohol 70% v/v

Purpose
Antiseptic

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

Warnings
• Flammable, keep away from fire or flame.
• Do not use with electrocautery procedures.
• 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.
• Allow to dry.
• Do not blot or wipe away.

Other Information
Store at room temperature between 59-86 °F (15-30 °C)

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

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

Principal Display Panel
Prod. #: 120-01U        NDC: 68356-120-XX
LORIS
Applicator containing a solution of 10% w/v Povidone-Iodine & 70% v/v Isopropyl Alcohol
Net content: 0.9 fl. oz (26 mL)
Antiseptic
STERILE Solution and Swab
Unless package is opened or damaged
For Hospital and Professional Use Only
MANUFACTURED BY:
LERNAPHARM (LORIS) INC.
VILLE ST-LAURENT
QC, CANADA H4S 1S3
LOT #: (XXXX)        EXP.: (MM-YYYY)

PROD. #: 120-01U        NDC: 68356-120-01

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Manufactured by: LemaPharm (Loris) Inc.
Ville St-Laurent, Qc, Canada H4S 1S3
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**Antiseptic**

**STERILE Solution and Swab**

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For Hospital and Professional Use Only

<table>
<thead>
<tr>
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</tr>
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<tbody>
<tr>
<td><strong>Active ingredients</strong></td>
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<td>Isopropyl Alcohol 70% v/v</td>
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LORIS 10% POVIDONE-IODINE AND 70% ISOPROPYL ALCOHOL SOLUTION
povidone-iodine and isopropyl alcohol liquid

Product Information

Product Type: HUMAN OTC DRUG
Item Code (Source): NDC:68356-120
Route of Administration: TOPICAL

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)</td>
<td>IODINE</td>
<td>100 g in 1 mL</td>
</tr>
<tr>
<td>Isopropyl Alcohol (UNII: ND2M416302)</td>
<td>ISOPROPYL ALCOHOL</td>
<td>0.7 mL in 1 mL</td>
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</table>

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tbody>
<tr>
<td>Anhydrous Citric Acid (UNII: XF417D3PSL)</td>
<td></td>
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<tr>
<td>Glycerin (UNII: PDC6A3C00X)</td>
<td></td>
</tr>
<tr>
<td>Nonoxynol-9 (UNII: 48Q180SHBT)</td>
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</tr>
<tr>
<td>Water (UNII: 059QF0K00R)</td>
<td></td>
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<tr>
<td>Sodium Hydroxide (UNII: 55X04QC32I)</td>
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</tr>
<tr>
<td>Sodium Phosphate, Dibasic (UNII: GR686LBA74)</td>
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</tr>
</tbody>
</table>

Packaging

Other information: Store at room temperature between 59-86 °F (15-30°C)

Inactive ingredients: Citric Acid, Glycerol, Nonoxynol-9, Purified Water, Sodium Hydroxide, Sodium Phosphate Dibasic.

Questions or comments?
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Manufactured by: LernaPharm (Loris) Inc.
Ville St-Laurent, Qc, Canada H4S 1S3

LOT #: (XXXX) EXP.: (MM-YYYY)
<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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</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:68356-120-01</td>
<td>1 in 1 POUCH</td>
<td>01/10/2016</td>
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<tr>
<td>1</td>
<td></td>
<td>26 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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<tr>
<td>OTC monograph not final</td>
<td>part333E</td>
<td>01/10/2016</td>
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</table>

**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>STERIS Isomedix Services</td>
<td></td>
<td>205475333</td>
<td>sterilize(68356-120)</td>
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</table>

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<tbody>
<tr>
<td>LernaPharm Loris Inc.</td>
<td></td>
<td>206940905</td>
<td>manufacture(68356-120), label(68356-120), pack(68356-120)</td>
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</table>

Revised: 10/2019

LernaPharm Loris Inc.