POVIDONE IODINE TOPICAL SOLUTION PAINT- povidone iodine 10% liquid
Jiangsu Province Jianerkang Medical Dressing Co., Ltd.

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.

Povidone Iodine Topical Solution Paint

Drug Facts

Active Ingredient
Povidone-Iodine, USP 10%
(1.0% available iodine)

Purpose
Antiseptic

Use
prepping intact skin and mucous membranes prior to surgery

Warnings
for external use only
avoid use on persons allergic to iodine

Stop using this product and ask a doctor if
• skin shows symptoms of irritation, sensitivity, redness, pain or swelling

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

Directions
Patient preoperative prep
• apply solution to operative site following povidone iodine scrub application
• using a circular motion, start at incision site and move outward
• remove all soiled underdrapes
• do not allow solution to pool

Other information
• store at room temperature
• avoid excessive heat (above 104 degrees F/40 degrees C)
• protect from freezing
• latex free
Inactive Ingredients
Citric acid, glycerol, nonylphenol ethoxylate, Purified Water, sodium hydroxide

Package Labeling

POVIDONE IODINE TOPICAL SOLUTION PAINT
povidone iodine 10% liquid

Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
<th>NDC: 34645-1041</th>
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</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>TOPICAL</td>
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Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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</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 ACETATE (UNII: DSO12WL7AU)</td>
<td></td>
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</tbody>
</table>
GLYCERIN (UNII: PDC6A3C0OX)
NONOXYNOL-9 (UNII: 48Q180SH9T)
WATER (UNII: 059QF0KO0R)
SODIUM HYDROXIDE (UNII: 55X04QC32I)

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>
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<td>NDC:34645-1041-1</td>
<td>88.5 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>03/31/2015</td>
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Marketing Information

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<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 not final</td>
<td>part333A</td>
<td>03/31/2015</td>
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Labeler - Jiangsu Province Jianerkang Medical Dressing Co., Ltd. (530968767)

Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<td>Jiangsu Province Jianerkang Medical Dressing Co., Ltd.</td>
<td></td>
<td>530968767</td>
<td>manufacture(34645-1041)</td>
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Revised: 12/2019