Betadine- povidone-iodine spray
Purdue Products LP

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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Betadine Spray

Povidone-iodine, 5%

Drug Facts

Active ingredient
Povidone-iodine, 5% (0.5% available iodine).

Purpose
Antiseptic

Uses

Patient pre-operative skin preparation
- 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
- If you are allergic to povidone-iodine or any other ingredients in this preparation

When using this product
- prolonged exposure to wet solution may cause irritation or, rarely, severe skin reactions
- in pre-operative prepping, avoid “pooling” beneath the patient

Stop use and ask a doctor if
- irritation, sensitization, or allergic reaction occurs and lasts for 72 hours. These may be signs of a serious condition.

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

Directions
- hold container about 4-6 inches from skin
- spray desired area n allow to dry
- may be bandaged
- replace cap after use

Other information
Betadine Spray
NDC 67618-148-03

Betadine Spray
NDC 67618-148-03

Inactive ingredients
citric acid, dibasic sodium phosphate, glycerin, nonoxynol-9, purified water

Dist. by: Purdue Products L.P., Stamford, CT 06901-3431
301821-0B

Betadine Spray
NDC 67618-148-03
<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)</td>
<td>Povidone-Iodine</td>
<td>.05 mL in 1 mL</td>
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### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tbody>
<tr>
<td>Citric Acid (UNII: 2968PHW8QP)</td>
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<tr>
<td>Sodium Phosphate, Dibasic (UNII: GR686LBA74)</td>
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<tr>
<td>Glycerin (UNII: PDC6A3C0OX)</td>
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<tr>
<td>Nonoxynol-9 (UNII: 48Q180SH9T)</td>
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<td>Water (UNII: 059QF0KO0R)</td>
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### Packaging

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<th>Item Code</th>
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<td>89 mL in 1 BOTTLE</td>
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### Marketing Information

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<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
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<td>OTC monograph not final</td>
<td>part333A</td>
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### Labeler

- **Purdue Products LP (141916531)**

### Establishment

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<th>Name</th>
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<td>Thatcher Company</td>
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<td>MANUFACTURE</td>
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Revised: 1/2011

Purdue Products LP