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® Solution**
10% Povidone-iodine

**Drug Facts**

**Active ingredient**
Povidone-iodine, 10% (1% 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**
- single use will reduce the risk of infection from extrinsic contamination
- 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**
- single use may prevent extrinsic contamination
- clean the operative site prior to surgery
- apply product and allow to dry
- may be covered with a bandage

**Other information**
- store in original container
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

**Inactive ingredients**
pareth 25-9, purified water, sodium hydroxide

Dist. by:
**Avrio Health L.P.**
Stamford, CT 06901-3431

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Betadine Solution 8 oz
NDC: 67618-150-09
### Product Information

**Product Type**
- HUMAN OTC DRUG

**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) (Iodine - UNII:9679TC07X4)</td>
<td>Iodine</td>
<td>10 mg in 1 mL</td>
</tr>
</tbody>
</table>

**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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</thead>
<tbody>
<tr>
<td>Water (UNII: 059QF0KO0R)</td>
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<tr>
<td>Sodium Hydroxide (UNII: 55X04QC32I)</td>
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<tr>
<td>C12-15 Pareth-9 (UNII: H3ZIY6WPIR)</td>
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### 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>237 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>06/01/1980</td>
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<td>6</td>
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<td>3780 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
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### Marketing Information

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<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>part333A</td>
<td>06/01/1980</td>
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**Labeler** - Avrio Health L.P. (141916531)

**Registrant** - Purdue Pharma LP (932323652)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
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<tbody>
<tr>
<td>Thatcher Company</td>
<td></td>
<td>041307356</td>
<td>MANUFACTURE(67618-150)</td>
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Revised: 11/2020

Avrio Health L.P.