BETADINE SURGICAL SCRUB- povidone-iodine solution
Avrio Health L.P.

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 Surgical Scrub

Povidone-iodine, 7.5%

Drug Facts

Active ingredient
Povidone-iodine, 7.5% (0.75% available iodine)

Purpose
Antiseptic

Uses
- for preparation of the skin prior to surgery
- helps to reduce bacteria that potentially can cause skin infection
- for handwashing to reduce bacteria on the skin
- significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care

Warnings
For external use only

Do not use this product
- in the eyes

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 and redness develop
- in rare instances of local irritation or sensitivity

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

Directions
A. Surgical hand scrub:
- wet hands with water
- spread about 5 cc (1 teaspoonful) of Scrub over both hands and forearms
- without adding more water, scrub thoroughly for 2 1/2 to 3 minutes
- use a sponge if desired. Clean thoroughly under fingernails.
• add a little water and develop copious suds. Rinse thoroughly under running water.
• repeat the entire procedure using another 5 cc of Scrub

B. **Antiseptic hand wash:**
• wet hands with water and pour about 5 cc of Scrub on hands
• rub hands vigorously together for at least 15 seconds, covering all surfaces
• rinse and dry with a disposable towel

C. **Patient pre-operative skin preparation:**
• single use only
• wet skin with water
• apply Scrub (1 cc is sufficient to cover an area of 20-30 square inches), develop lather and
  scrub thoroughly for about 5 minutes
• rinse off using sterile gauze saturated with water
• the area may then be painted with BETADINE Solution and allowed to dry

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

**Inactive ingredients**
Ammonium nonoxynol-4 sulfate, nonoxynol-9, purified water, sodium hydroxide

Dist. by: **Avrio Health L.P. Stamford, CT 06901-3431**
304954-0A

Betadine Surgical Scrub
NDC 67618-150-17
BETADINE SURGICAL SCRUB
povidone-iodine solution

Product Information

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<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:67618-151</th>
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<td>Route of Administration</td>
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Active Ingredient/Active Moiety

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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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**POVIDONE-IODINE** (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)  
IODINE .075 mg in 1 mL

**Inactive Ingredients**

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<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<td>AMMONIUM NONOXYNOL-4 SULFATE</td>
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<td>NONOXYNOL-9</td>
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**Packaging**

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**Marketing Information**

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**Labeler** - Avrio Health L.P. (141916531)

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

**Establishment**

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<th>Name</th>
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Revised: 10/2018

Avrio Health L.P.