

**BETADINE- povidone iodine liquid**  
**Xttrium Laboratories, Inc.**

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**0.5% Betadine Gargle 8oz**

**Active Ingredient**

Povidone-iodine, 0.5%

**Purpose**

Antiseptic

**Warning**

**Sore Throat Warning:** Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor.

**Do not use this product**

- for more than 7 days unless directed by a dentist or doctor
- if you are allergic to povidone-iodine or any other ingredients in this product
- if you have any thyroid conditions

**When using this product**

- do not get into eyes. If contact occurs, rinse eyes thoroughly with water. If irritation persists, consult a doctor
- do not swallow
- do not use with hydrogen peroxide

**Stop use and ask a doctor**

- symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens
- swelling, rash, or fever develops

**If pregnant or breast-feeding**, ask a health professional before use.

For the temporary relief of occasional sore throat

Keep out of reach of children. In case more than used for gargling is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

DO NOT SWALLOW

**Adults and children 12 years and older:**

- Gargle with 10 ml full strength for 30 seconds, then spit out
- Use only with dosing cup provided
- Use up to 4 times daily

**Children under 12:** Do not use.

**Other information**

- store at 25°F (77°F); excursions permitted between 15°-30°C (59°-86°F)
- may stain clothing or dental work
- avoid contact with jewelry, especially silver

**Inactive Ingredients**

citric acid, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium hydroxide.

**Questions or comments?**

1-833-288-2684

<b>BETADINE</b> ANTISEPTIC 0.5% POVIDONE-IODINE ANTISEPTIC GARGLE	<b>Drug Facts</b>	<b>BETADINE</b> ANTISEPTIC
<b>SORE THROAT GARGLE</b> Treats & Relieves Sore Throat Symptoms	<b>Active ingredient</b> Povidone-iodine, 0.5% (0.05% available iodine)....., Antiseptic	✓ Fast Acting Antiseptic
<b>MINT FLAVOR</b>	<b>Purpose</b> Antiseptic	✓ Kills Germs in Mouth*
<b>8 FL OZ (237 mL)</b>	<b>Uses</b> ■ For the temporary relief of occasional sore throat	✓ Medicated Gargle
	<b>Warnings</b> <b>Sore Throat Warning:</b> Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor.	*Temporarily kills germs normally found in mouth
	<b>Do not use this product</b> ■ for more than 7 days unless directed by a dentist or doctor ■ if you are allergic to povidone-iodine or any other ingredients in this product ■ if you have any thyroid conditions	Do not use if seal under cap is missing or damaged.
	<b>When using this product</b> ■ do not get into eyes. If contact occurs, rinse eyes thoroughly with water. If irritation persists, consult a doctor ■ do not swallow ■ do not use with hydrogen peroxide	<b>Distributed by:</b> Atlantis Consumer Healthcare Inc. Bridgewater, NJ 08807 USA 1-833-288-2684 © 2024 Atlantis Consumer Healthcare Inc.
	<b>Stop use and ask a doctor if</b> ■ symptoms do not improve in 7 days ■ irritation, pain, or redness persists or worsens ■ swelling, rash, or fever develops	A0324 401308BTLBL
	<b>If pregnant or breast-feeding,</b> ask a health professional before use. <b>Keep out of reach of children.</b> In case more than used for gargling is accidentally swallowed, get medical help or contact a Poison Control Center right away.	
	<b>Directions</b> DO NOT SWALLOW <b>Adults and children 12 years and older:</b> ■ Gargle with 10 mL full strength for 30 seconds, then spit out ■ Use only with dosing cup provided ■ Use up to 4 times daily <b>Children under 12:</b> Do not use.	
	<b>Other information</b> ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ may stain clothing or dental work ■ avoid contact with jewelry, especially silver	
	<b>Inactive ingredients</b> citric acid, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium hydroxide.	
	<b>Questions or comments?</b> 1-833-288-2684	



## BETADINE

povidone iodine liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0116-0181
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	0.05 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

**ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL)

**WATER** (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-0181-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/07/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	11/07/2024	

**Labeler** - Xttrium Laboratories, Inc. (007470579)

**Registrant** - Xttrium Laboratories, Inc. (007470579)

### Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-0181)

Revised: 11/2024

Xttrium Laboratories, Inc.