

**BETADINE GARGLE- povidone-iodine solution**  
**Atlantis Consumer Healthcare, Inc.**

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**BETADINE® Sore Throat Gargle**  
**0.5% Povidone-iodine**

***Drug Facts***

***Active ingredient***

Povidone-iodine, 0.5%(0.05% available iodine)

***Purpose***

Antiseptic

***Uses***

- For the temporary relief of occasional sore throat

***Warnings***

**SoreThroat Warning:** Severe or persistent sore throat or sore throataccompanied by high fever, headache, nausea, and vomiting may be serious.Consult doctor promptly. Do not use more than 2 days or administerto 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 ingredientsin this product
- if you have any thyroid conditions

**When using this product**

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

**Stop use and ask a doctor if**

- 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.

**Keep out of reach of children.** In case more than used for gargling is accidentally swallowed, getmedical 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***

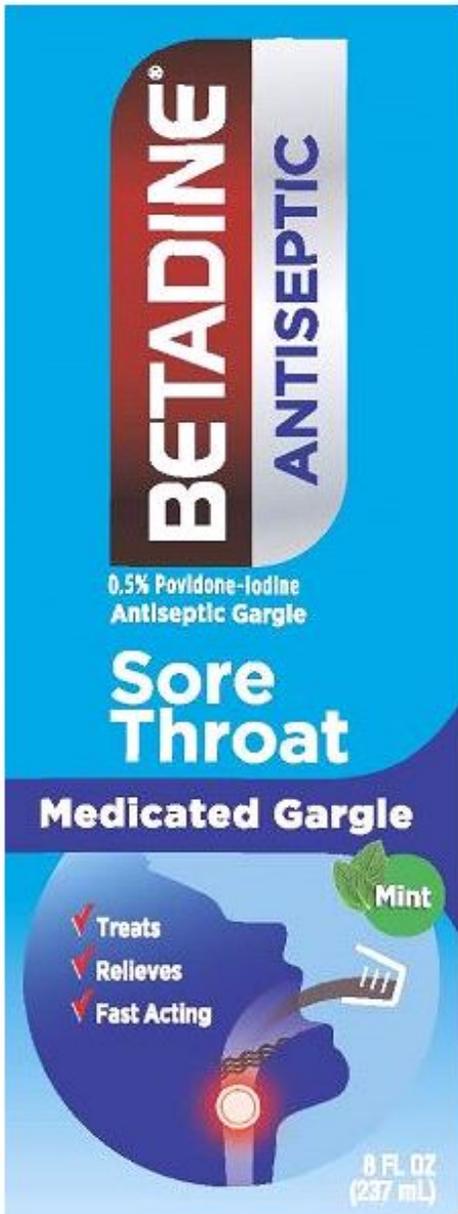
- store at 25°C (77°F); excursions permitted between 15°-30°C(59°-86°F)
- may stain clothing or dental work
- avoid contact with jewelry, especially silver

***Inactive ingredients***

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

Dist. by: **Avrio Health L.P. Stamford, CT 06901-3431**  
305586-0E

Betadine Gargle Carton  
NDC: 67618-181-08



## BETADINE GARGLE

povidone-iodine solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67618-181
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	.05 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67618-181-08	1 in 1 CARTON	06/15/2020	
1		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	06/15/2020	

**Labeler** - Atlantis Consumer Healthcare, Inc. (118983925)

**Registrant** - Atlantis Consumer Healthcare, Inc. (118983925)

Revised: 12/2023

Atlantis Consumer Healthcare, Inc.