

**POVIDONE IODINE- povidone iodine gargle 0.5% liquid**  
**Pharma Nobis, LLC**

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**Private Label Povidone Iodine Gargle 0.5%**

Drug Facts

**Active Ingredient**

Povidone-Iodine 0.5%  
(0.05% available iodine)

**Purpose**

Antiseptic

**Use**

For the temporary relief of occasional sore throat.

**Warnings**

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.

**Stop use and consult a doctor if**

Symptoms do not improve in 7 days.  
Irritation, pain or redness persists or worsens.  
Swelling, rash or fever develops.

**When using this product do not**

Get into eyes. If contact occurs, rinse eyes thoroughly with water. If irritation persists, consult a doctor.  
Swallow.  
Use with hydrogen peroxide.

**Keep out of reach of children.**

In case more than used for gargling is swallowed, get medical help or contact a Poison Control Center immediately.

## **Directions**

DO NOT SWALLOW

Adults and children 12 years and older:

- Gargle with 10mL 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°C and 30°C (59°F-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.

## **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.

## **If pregnant or breast-feeding**

Ask a health professional before use.

## **Purdue Gargle Label**

0.5% POVIDONE-IODINE  
ANTISEPTIC GARGLE

# BETADINE ANTISEPTIC

# BETADINE ANTISEPTIC

0.5% Povidone-Iodine  
Antiseptic Gargle

## Sore Throat

### Medicated Gargle



- Treats
- Relieves
- Fast Acting

8 FL. OZ.  
(237 mL)

- Temporarily reduces germs normally found in the mouth\*
- Treats and relieves sore throat symptoms
- Fast acting gargle

## Feel the sign? BETADINE®

Antiseptic Gargle

## Power of BETADINE® antiseptic action

Drug Facts	
<b>Active ingredient</b>	<b>Purpose</b>
Povidone-iodine, 0.5% (0.05% available iodine)	Antiseptic
<b>Uses</b>	
<ul style="list-style-type: none"> <li>For the temporary relief of occasional sore throat</li> </ul>	
<b>Warnings</b>	
<p><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.</p>	
<b>Do not use this product</b>	
<ul style="list-style-type: none"> <li>for more than 7 days unless directed by a dentist or doctor</li> <li>if you are allergic to povidone-iodine or any other ingredients in this product</li> <li>if you have any thyroid conditions</li> </ul>	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>do not get into eyes. If contact occurs, rinse eyes thoroughly with water. If irritation persists, consult a doctor</li> <li>do not swallow</li> <li>do not use with hydrogen peroxide</li> </ul>	
<b>Stop use and ask a doctor if</b>	
<ul style="list-style-type: none"> <li>symptoms do not improve in 7 days</li> <li>irritation, pain, or redness persists or worsens</li> <li>swelling, rash, or fever develops</li> </ul>	
<p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><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. ▶</p>	

<b>Drug Facts</b> (continued)
<b>Directions</b>
<p><b>DO NOT SWALLOW</b></p> <p><b>Adults and children 12 years and older:</b></p> <ul style="list-style-type: none"> <li>Gargle with 10 ml full strength for 30 seconds, then spit out</li> <li>Use only with dosing cup provided</li> <li>Use up to 4 times daily</li> </ul> <p><b>Children under 12:</b> Do not use.</p>
<b>Other information</b>
<ul style="list-style-type: none"> <li>store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)</li> <li>may stain clothing or dental work</li> <li>avoid contact with jewelry, especially silver</li> </ul>
<b>Inactive ingredients</b>
citric acid, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium hydroxide.
<b>Questions or comments?</b> 1-800-627-0624 (8am-5pm, EST, Mon. - Fri.)

Use only with dosing cup provided. Avoid swallowing of gargle.

**Write to:** Avrio Health, L.P.  
Department, 10000 North Loop West  
P.O. Box 1000000

**Avrio Health, L.P.**  
Povidone and Iodine are registered trademarks of Avrio Health, L.P.

020117-08





# BETADINE<sup>®</sup> ANTISEPTIC

0.5% Povidone-Iodine  
Antiseptic Gargle

## Sore Throat

### Medicated Gargle



8 FL OZ (237 ml)

Drug Facts	
<b>Active ingredient</b> Povidone-iodine, 0.5% (0.05% available iodine)	<b>Purpose</b> Antiseptic
<b>Uses</b> ■ For the temporary relief of occasional sore throat	
<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.	
<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	
<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>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	
<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> 1-888-827-0624 (8am-5pm, EST, Mon. - Fri.).	

- Temporarily reduces germs normally found in the mouth\*
  - Treats and relieves sore throat symptoms
  - Fast acting gargle
- \*based on laboratory data  
Do not use if seal under cap is missing or damaged.

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Stamford, CT 06901-3431  
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0.5% Povidone-Iodine  
Antiseptic Gargle

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8 FL OZ (237 ml)

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<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.	
<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	
<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>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	
<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> 1-888-827-0624 (8am-5pm, EST, Mon. - Fri.).	

- Temporarily reduces germs normally found in the mouth\*
- Treats and relieves sore throat symptoms
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\*based on laboratory data

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0.5% POVIDONE-IODINE  
ANTISEPTIC GARGLE

**BETADINE**  
ANTISEPTIC

**BETADINE**  
ANTISEPTIC

0.5% Povidone-iodine  
Antiseptic Gargle

**Sore  
Throat**

Medicated Gargle

Mint

- Treats
- Relieves
- Fast Acting

8 FL. OZ.  
(237 mL)

- Temporarily reduces germs normally found in the mouth\*
- Treats and relieves sore throat symptoms
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Feel the sign?  
**BETADINE**

\*Based on laboratory data

Power of  
**BETADINE**  
antiseptic  
action

**Drug Facts**

**Active ingredient**      **Purpose**  
Povidone-iodine, 0.5%  
(0.05% available iodine)      Antiseptic

**Uses**  
• For the temporary relief of occasional sore throat

**Warnings**  
**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 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 one is gargling is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Drug Facts (continued)**

**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 cap provided.  
• Use up to 4 times daily.  
**Children under 12:** Do not use.

**Other information**  
• **STPP** 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.

**Questions or comments?** 1-800-827-0824  
(Mon-Fri, EST, Mon-Fri,).

**Do not use if liquid seal on cap is broken or damaged.**

**Manufacturer:** Avrio Health, L.P.  
Shrewsbury, CT 06081-0801  
[www.Betadine.com](http://www.Betadine.com)

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302289-01





**BETADINE**  
ANTISEPTIC

0.5% Povidone-Iodine  
Antiseptic Gargle

**Sore Throat  
Gargle**

Mint



8 FL OZ (237 ml)

**Drug Facts**

**Active Ingredients**

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**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 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, 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°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

**Questions or comments?**

1-888-827-0624 (Mon-Fri, 9am-5pm, EST, Mon-Fri)

- ✓ Treats
- ✓ Relieves
- ✓ Fast Acting

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305534-0A



**Drug Facts**  
**Active Ingredient** Povidone-iodine, 0.5% (0.06% available iodine)  
**Purpose** Antiseptic

**Uses**  
For the temporary relief of occasional sore throat

**Warnings**  
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**Inactive ingredients**  
citric acid, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium hydroxide

**Questions or comments?** 1-888-827-0624 (Mon-Fri, 9am-5pm, EST, Mon-Fri)

Do not use if liquid level in carton falls or open or damaged.

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305534-0E



NON VARNISH  
LOT/EXP

# POVIDONE IODINE

povidone iodine gargle 0.5% liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82645-908
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>POVIDONE-IODINE</b> (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	5 mg in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PEPPERMINT</b> (UNII: V95R5KMY2B)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:82645-908-98	1 in 1 CARTON	06/10/2020	
1		237 mL in 1 CONTAINER; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M003	06/10/2020	

**Labeler** - Pharma Nobis, LLC (118564114)

**Registrant** - Pharma Nobis, LLC (118564114)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
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Pharma Nobis, LLC	118564114	manufacture(82645-908) , analysis(82645-908) , pack(82645-908) , label(82645-908)
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Revised: 12/2023

Pharma Nobis, LLC