

POVIDONE IODINE- povidone iodine gargle 0.5% liquid
Humco Holding Group, Inc.

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

BETADINE
ANTISEPTIC

0.5% Povidone-Iodine
Antiseptic Gargle

**Sore
Throat**

Medicated Gargle



8 FL OZ (237 ml)

Drug Facts	
Active ingredient Povidone-iodine, 0.5% (0.05% available iodine)	Purpose 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 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 (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

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Stamford, CT 06901-3431
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305583-0B



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
- Fast acting gargle

Feel the sign?
BETADINE

*Based on laboratory data

Power of
BETADINE
antiseptic
action

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

- 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? 1-800-827-0824 (Rain-Garg, EST. Mon. - Fri.)

Do not use if liquid has an orange-brown color or clumps.

Manufacturer: Avrio Health, L.P.
Shrewsbury, CT 06081-0801
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302289-01

AVRIO
health



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 accidentally swallowed, get medical help or contact a Poison Control Center right away.

BETADINE
ANTISEPTIC

0.5% Povidone-Iodine
Antiseptic Gargle

**Sore Throat
Gargle**

Mint



8 FL OZ (237 ml)

Drug Facts

Active Ingredients

Povidone-iodine, 0.5% (0.06% available iodine)

Purpose

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 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 (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 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.)

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

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305534-0E

Avrio health



NON VARNISH
LOT/EXP

POVIDONE IODINE

povidone iodine gargle 0.5% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0395-9128
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
MENTHOL (UNII: L7T10EIP3A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEPPERMINT (UNII: V95R5KMY2B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0395-9128-98	1 in 1 CARTON	06/10/2020	
1		237 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

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

Labeler - Humco Holding Group, Inc. (825672884)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
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Pharma Nobis, LLC	118564114	manufacture(0395-9128) , analysis(0395-9128) , pack(0395-9128) , label(0395-9128)
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Revised: 12/2023

Humco Holding Group, Inc.