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 voniting 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 iritation 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, saccarin sodium, sodium hydroxide.

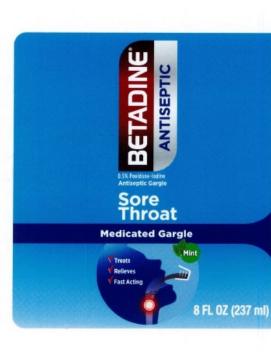
Do not use this product

- 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



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 derfist or doctor ■ if you are allergic to povidone-lodine 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 percoide

Stop use and ask a doctor If symptoms do not improve in 7 days in irritation, pain, or redness persists

or worsens swelling, rash, or fever develops

If pregnant or breast-leeding, 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.

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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

Dist by: Avrio Health L.P. Stamford, CT 08901-3431 2021 Avrio Health L.P.

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Power of action

BETADINE antiseptic

Feel the sign?

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Sore Throat





Drug Facts

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Brug Facts (continued) Directions

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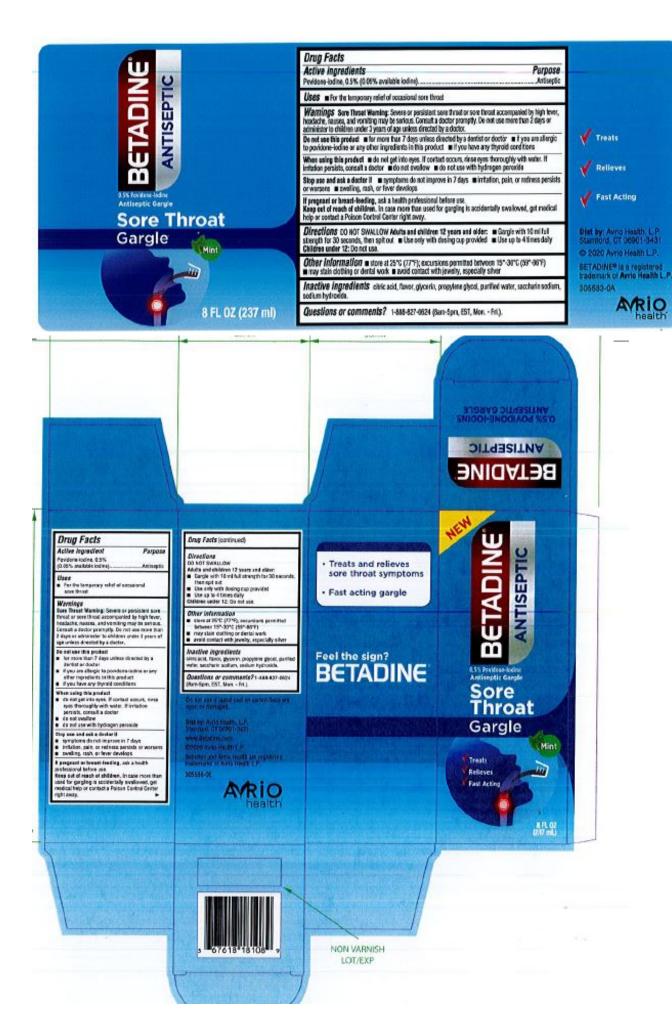
Questions or comments? 1-888-827-9824

(Barri-Sorn, EST, Mon. - frt.).

BETADINE

INTISEPTIC

ANTISEPTIC *SNIGATSB*



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	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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

Pharma Nobis,	118564114	manufacture(0395-9128) , label(0395-9128)	analysis(0395-9128),	pack(0395-9128) ,
LLC	110504114	label(0395-9128)		

Revised: 12/2023 Humco Holding Group, Inc.