

**POVIDONE IODINE- povidone iodine oral rinse 0.5% liquid**  
**Humco Holding Group, Inc.**

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**Private Label Povidone Iodine Oral Rinse 0.5%**

Drug Facts

**Active Ingredient**

Povidone-Iodine 0.5%  
(0.05% available iodine)

**Purpose**

Oral Antiseptic

**Use**

For preparation of the oral mucosa prior to injection, dental surgery or tooth extraction.

**Warnings**

Do not use this product

- for more than 7 days unless directed by a dentist or doctor
- in children under 12 years of age 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

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

### **Directions**

- Use full strength.
- Apply 10 to 20 milliliters of solution to the operative site. Instruct the patient to rinse for 30 seconds and then spit out.
- Wait 2 minutes, and apply another 10 to 20 milliliters of solution to the operative site. Instruct the patient to rinse again for 30 seconds and then spit out.
- With a standard syringe and a blunt, angulated needle, irrigate the operative site and the surrounding gingival mucosa for 1 minute with 10 to 20 milliliters of the solution. Instruct the patient to spit out the solution after the irrigation procedure.

### **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 Oral Rinse Label**

NDC 67618-182-20

**BETADINE**  
ANTISEPTIC

# Oral Rinse

Sales Sample. Not labeled for consumer use or retail sale. For professional use only.

0.5% Povidone-Iodine  
Oral Antiseptic  
0.67 FL OZ (20 ml)



**Active ingredient:** Povidone-iodine, 0.5%

**Uses:** ■ Use full strength for the preparation of the oral mucosa prior to certain dental procedures (see commercial packaging or betadine.com for complete directions and Drug Facts)

■ Rinse 30 sec. with 10-20 ml solution and spit

**WARNINGS:** DO NOT SWALLOW

■ Do not use if you are allergic to any of the ingredients or if you have any thyroid conditions

■ Do not get into the eyes

■ Do not use with hydrogen peroxide

**Inactive Ingredients:** citric acid, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium hydroxide

**Questions?** 1-888-827-0624

305863-0A

Dist by: Avrio Health,  
L.P., Stamford, CT  
06901-3431

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NOT FOR RETAIL SALE  
For Professional Use Only  
NDC 67618-182-08

**BETADINE**  
ANTISEPTIC

# Oral Rinse



0.5% Povidone-Iodine  
Oral Antiseptic

8 FL OZ (237 ml)

<b>Drug Facts</b>	
<b>Active ingredient</b> Povidone-iodine, 0.5% (0.05% available iodine)	<b>Purpose</b> Oral Antiseptic
<b>Uses</b> ■ For preparation of the oral mucosa prior to injection, dental surgery, or tooth extraction	
<b>Warnings</b> Do not use this product ■ for more than 7 days unless directed by a dentist or doctor ■ in children under 12 years of age 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 or dentist if</b> ■ 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 rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> ■ Use full strength. ■ Apply 10 to 20 milliliters of solution to the operative site. Instruct the patient to rinse for 30 seconds and then spit out. ■ Wait 2 minutes, and apply another 10 to 20 milliliters of solution to the operative site. Instruct the patient to rinse again for 30 seconds and then spit out. ■ With a standard syringe and a blunt, angulated needle, irrigate the operative site and the surrounding gingival mucosa for 1 minute with 10 to 20 milliliters of the solution. Instruct the patient to spit out the solution after the irrigation procedure.	
<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 (Sat-Sun, EST, Mon - Fri).	

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Stamford, CT 06901-3431

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305765-08 **ARIO** health



## POVIDONE IODINE

povidone iodine oral rinse 0.5% liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0395-9136
<b>Route of Administration</b>	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
<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: 059QF0KO0R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PEPPERMINT</b> (UNII: V95R5KMY2B)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0395-9136-98	237 mL in 1 CONTAINER; Type 0: Not a Combination Product	01/06/2021	
2	NDC:0395-9136-23	20 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/01/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	01/06/2021	

**Labeler** - Humco Holding Group, Inc. (825672884)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(0395-9136) , analysis(0395-9136) , pack(0395-9136) , label(0395-9136)

Revised: 12/2023

Humco Holding Group, Inc.