

BETADINE ANTISEPTIC ORAL RINSE- povidone-iodine solution
Atlantis Consumer Healthcare, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

BETADINE® Antiseptic Oral Rinse
0.5% Povidone-iodine
Oral Antiseptic

Drug Facts

Active ingredient

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

Purpose

Oral Antiseptic

Uses

- 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

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 or dentist 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 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°-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**
305765-0B

Betadine Oral Rinse
NDC: 67618-182-08

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)

BETADINE ANTISEPTIC ORAL RINSE

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67618-182
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
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67618-182-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	02/08/2021	

Labeler - Atlantis Consumer Healthcare, Inc. (118983925)

Registrant - Atlantis Consumer Healthcare, Inc. (118983925)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	MANUFACTURE(67618-182)

Revised: 6/2023

Atlantis Consumer Healthcare, Inc.