

**BETADINE SOLUTION- povidone-iodine solution**  
**Atlantis Consumer Healthcare, Inc.**

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**BETADINE® Solution**  
**10% Povidone-iodine**

***Drug Facts***

***Active ingredient***

Povidone-iodine, 10%(1% available iodine)

***Purpose***

Antiseptic

***Uses***

**Patient pre-operative skin preparation**

- for preparation of the skin prior to surgery
- helps reduce bacteria that potentially can cause skin infection

***Warnings***

**For external use only**

**Do not use**

- in the eyes
- if you are allergic to povidone-iodine or any other ingredients in this preparation

**When using this product**

- single use will reduce the risk of infection from extrinsic contamination
- prolonged exposure to wet solution may cause irritation or, rarely, severe skin reactions
- in pre-operative prepping, avoid “pooling” beneath the patient

**Stop use and ask a doctor if**

- irritation, sensitization, or allergic reaction occurs and lasts for 72 hours. These may be signs of a serious condition.

**Keep out of reach of children.**

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

***Directions***

- single use may prevent extrinsic contamination
- clean the operative site prior to surgery
- apply product and allow to dry
- may be covered with a bandage

***Other information***

- store in original container
- store at 25°C (77°F); excursions permitted between 15°-30°C(59°-86°F)

***Inactive ingredients***

pareth 25-9, purified water, sodium hydroxide

Dist. by:

**Avrio Health L.P.**  
**Stamford, CT 06901-3431**

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BetadineSolution 8 oz  
NDC: 67618-150-09

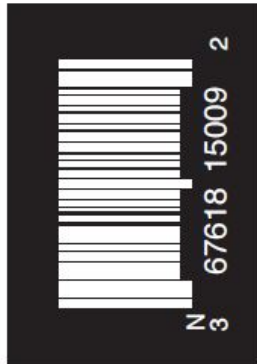
**Not for Retail Sale**

NDC 67618-150-09 NSN 6505-00-286-7011  
For Professional and Hospital Use Only

# BETADINE® Solution

10% Povidone-iodine

**Antiseptic  
Non-Sterile  
Solution**  
Topical  
Bactericide



8 fl oz  
(237 ml)

### Drug Facts

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**Questions?** 1-888-827-0624 (8am-5pm, EST, Mon.-Fri.).

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## BETADINE SOLUTION

povidone-iodine solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67618-150
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>POVIDONE-IODINE</b> (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>C12-15 PARETH-9</b> (UNII: H3ZII6WP1R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67618-150-09	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1980	
2	NDC:67618-150-05	14.8 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1980	
3	NDC:67618-150-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1980	
4	NDC:67618-150-17	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1980	
5	NDC:67618-150-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1980	08/31/2024
6	NDC:67618-150-01	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1980	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003	06/01/1980	

**Labeler** - Atlantis Consumer Healthcare, Inc. (118983925)

**Registrant** - Atlantis Consumer Healthcare, Inc. (118983925)

Revised: 12/2023

Atlantis Consumer Healthcare, Inc.