BETADINE SOLUTION- 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® Solution
10% Povidone-iodine

Drug Facts

Active ingredient

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

Purpose

First aid antiseptic

Uses

First aid to help prevent infection in minor
- cuts
- scrapes
- burns

Warnings For external use only

Do not use
- in the eyes
- over large areas of the body
- if you are allergic to povidone-iodine or any other ingredients in this preparation

Ask a doctor before use if you have
- deep or puncture wounds
- serious burns
- animal bites

Stop use and ask a doctor if
- the condition persists or gets worse
- you need to use this product for more than 1 week

Keep out of reach of children.
If swallowed, get medical help or contact a Poison Control Center right away

Directions

- clean the affected area
- apply a small amount of product to the area 1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first

Other information

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

Inactive ingredients

citric acid, disodium phosphate, glycerin, nonoxynol-9, purified water, sodium hydroxide

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

305541-0D

Betadine Solution 8 fl oz Bottle
NDC: 67618-150-08

BETADINE SOLUTION

povidone-iodine solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67618-150
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC, MONOHYDRATE (UNII: BWZ7K44R51)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67618-150-08	237 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 not final	part333A	06/01/1980	

Labeler - Atlantis Consumer Healthcare, Inc. (118983925)

Registrant - Atlantis Consumer Healthcare, Inc. (118983925)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	MANUFACTURE(67618-150)

Revised: 6/2023 Atlantis Consumer Healthcare, Inc.