BETADINE- povidone-iodine spray Atlantis Consumer Healthcare, Inc.

BETADINE® Spray 5% Povidone-iodine

Drug Facts

Active ingredients

Povidone-iodine, 5%(0.5% available iodine)

Purpose

First aid Antiseptic

Uses

First aidto 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 useif 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 Centerright away.

Directions

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

Other information

store at25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) Do NotFreeze

Inactive ingredients

citric acid, disodium phosphate, glycerin,poloxamer 407, potassium iodate, purified water, sodium hydroxide

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

Betadine 3oz Spray NDC: 67618-160-03



Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration Product Type 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		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
SODIUM PHOSPHATE, DIBASIC, MONOHYDRATE (UNII: BWZ 7K44R51)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLOXAMER 407 (UNII: TUF2IVW3M2)			
POTASSIUM IODATE (UNII: 1139E44NHL)			
WATER (UNII: 059QF0KO0R)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			

F	Packaging					
4	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:67618-160- 03	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/1992			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M003	04/15/1992		

Labeler - Atlantis Consumer Healthcare, Inc. (118983925)

Registrant - Atlantis Consumer Healthcare, Inc. (118983925)

Revised: 12/2023 Atlantis Consumer Healthcare, Inc.