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

BETADINE® Solution 10% Povidone-iodine

Drug Facts

Active ingredient

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

Purpose

First aid antiseptic

Uses

First aid to helpprevent infection in minor

- cuts
- scrapes
- burns

WarningsFor 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, getmedical 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 timesdaily
- 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, disodiumphosphate, glycerin, nonoxynol-9, purified water, sodium hydroxide

Dist.by:

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

305541-0D

BetadineSolution 6 fl oz Bottle

NDC: 67618-150-18



BetadineSolution 8 fl oz Bottle

NDC: 67618-150-08





10% POVIDONE-IODINE

First Aid **Antiseptic** Solution



- √ Ideal for Minor Cuts, Wounds, Scrapes & Burns
- √ Kills 99.9% of Germs* To Prevent Infection
- √ Works in Seconds[†]
- √ No Stinging or Burning







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.First aid antiseptic (1% available iodine).

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Questions? 1-833-288-2684

Do not use if seal under cap is missing or damaged.

*commonly associated with skin infections

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Visit www.Betadine.com for more information.

FIRST AID FOR THE WHOLE

Helps protect against skin infection

Golden brown color indicates area treated



Dist. by: Atlantis Healthcare Inc. Bridgewater, NJ 08807 USA

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Strength

8 fl oz (237 mL)

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

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

Inactive Ingredients

Ingredient Name

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

SODIUM PHOSPHATE, DIBASIC, MONOHYDRATE (UNII: BWZ 7K44R51)

GLYCERIN (UNII: PDC6A3C0OX) NONOXYNOL-9 (UNII: 48Q180SH9T)

WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04OC32I)	

l	P	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1		237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1980			
	2	NDC:67618-150- 18	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/09/2020			

Marketing In	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: 4/2024 Atlantis Consumer Healthcare, Inc.