

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
ANTISEPTIC

10% POVIDONE-IODINE
FIRST AID ANTISEPTIC

Do not use if seal under cap is missing or damaged.
*Refers to Povidone-iodine 10%

*Our promise or your money back.
Visit www.Betadine.com for details.



BETADINE
ANTISEPTIC

HOSPITAL TRUSTED SINCE 1955

LOTEXP

305901-08

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

FIRST AID FOR THE WHOLE FAMILY

Helps protect against skin infection

Golden brown color indicates area treated



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

AVRIO health

Solution

NO-STING PROMISE*

Maximum Strength* Germ Killing for Minor Cuts, Scrapes & Burns



8 fl oz (237ml)

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: BWZ 7K44R51)	
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.