BETADINE- 10% povidone-iodine liquid Xttrium Laboratories, Inc

Betadine 10% OTC 6oz and 8oz

Active Ingredient

Povidone-iodine, 10%

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 bums ■ 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

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

Questions?

1-833-288-2684

Principle Display Panel

Betadine Antiseptic

67618-150-18



Betadine Antiseptic 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







Uses first aid to help prevent infection in minor ■ cuts ■ scrapes

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

Stop use and ask a doctor if the condition persists or gets worse

Keep out of reach of children. If swallowed, get medical help or

you need to use this product for more than 1 week

contact a Poison Control Center right away



FIRST AID
FOR THE WHOLE
FAMILY

Purpose

.First aid antiseptic

Helps protect against skin infection

Golden brown color indicates area treated

Visit www.Betadine.com for more information.

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

*commonly associated with skin infections †based on in vitro lab data,

Directions

Drug Facts

Active ingredient

Warnings For external use only

■ serious burns ■ animal bites

Povidone-iodine, 10%

(1% available iodine)..

burns

- 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

Questions? 1-833-288-2684



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

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8 fl oz (237 mL)

BETADINE

10% povidone-iodine liquid

Product Information

WATER (UNII: 059QF0KO0R)

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0116-0150

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

POVIDONE-IODINE (UNII: 85H0HZ U99M) (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) NONOXYNOL-9 (UNII: 48Q180SH9T)

SODIUM HYDROXIDE (UNII: 55X04QC32I)	
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GLYCERIN (UNII: PDC6A3C0OX)

l	Packaging						
	# Item	Code	Package Description	Marketing Start Date	Marketing End Date		
	1 NDC:0		237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/06/2024			
	2 NDC:0		177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/06/2024			

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC Monograph Drug	M003	11/06/2024					

Labeler - Xttrium Laboratories, Inc (007470579)

Registrant - Xttrium Laboratories, Inc (007470579)

Establishment										
Name	Address	ID/FEI	Business Operations							
Xttrium Laboratories, Inc.		007470579	manufacture(0116-0150)							

Revised: 11/2024 Xttrium Laboratories, Inc