## BETADINE- povidone-iodine liquid Xttrium Laboratories, Inc.

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### 5% Betadine Spray 3oz

Povidone-iodine, 5%

First aid antiseptic

first aid to help prevent infection in minor

■ cuts ■ scrapes ■ burns

### Warnings For external use only

**Do not use**  $\blacksquare$  in the eyes  $\blacksquare$  over large areas of the body  $\blacksquare$  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

- clean the affected area
- spray a small amount

of product on the area 1 to 3 times daily

- may be covered with a sterile bandage
- if bandaged, let dry first
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) Do Not Freeze

pareth 25-9, purified water, sodium hydroxide

1-833-288-2684



## **BETADINE**

povidone-iodine liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0116-0160

Route of Administration 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		
C12-15 PARETH-9 (UNII: H3ZIY6WP1R)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
WATER (UNII: 0590F0KO0R)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116- 0160-03	88.7 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/07/2024	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M003	11/07/2024		

# Labeler - Xttrium Laboratories, Inc. (007470579)

# **Registrant -** Xttrium Laboratories, Inc. (007470579)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Xttrium Laboratories, Inc.		007470579	manufacture(0116-0160)		

Revised: 11/2024 Xttrium Laboratories, Inc.