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

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## 7.5% Betadine Surgical Scrub 4oz and 1 gallon

## **Active Ingredient**

Povidone-Iodine, 7.5%

# **Purpose**

Antiseptic

#### Uses

- for preparation of the skin prior to surgery
- helps to reduce bacteria that potentially can cause skin infection
- for handwashing to reduce bacteria on the skin
- significantly reduces the number of microorganisms on the hands forearms prior to surgery or patient care

## **Warnings**

# For external use only

**Do not use** ■ in the eyes

When using this product ■ prolonged exposure to wet solution may cause irritation or, rarely, severe skin reactions

■ in pre-operative prepping, avoid "pooling" beneath the patient

Stop use and ask a doctor ■ if irritation and redness develop

■ in rare instances of local irritation or sensitivity

**Keep out of reach of children**. If swallowed, get medical help or contact a Poison Control Center right away

#### **Directions**

# A. Surgical hand scrub:

- wet hands with water
- spread about 5 cc (1 teaspoonful) of Scrub over both handsand forearms
- without adding more water, scrub thoroughly for 2 1/2 to3 minutes
- use a sponge if desired. Clean thoroughly under fingernails.
- add a little water and develop copious suds. Rinse thoroughlyunder running water.
- repeat the entire procedure using another 5 cc of Scrub

# B. Antiseptic hand wash:

• wet hands with water and pour about 5 cc of Scrub on hands

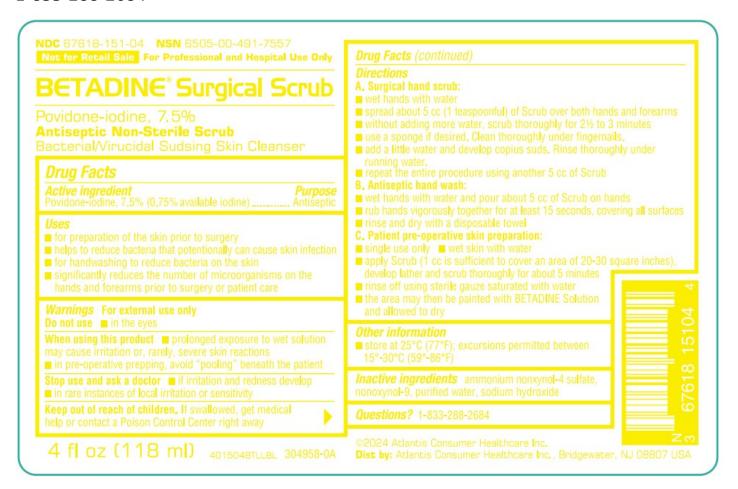
- rub hands vigorously together for at least 15 seconds, coveringall surfaces
- rinse and dry with a disposable towel
- C. Patient pre-operative skin preparation:
- single use only
- wet skin with water
- apply Scrub (1 cc is sufficient to cover an area of 20-30 square inches), develop lather and scrub thoroughly for about 5 minutes
- rinse off using sterile gauze saturated with water
- the area may then be painted with BETADINE Solution and allowed to dry
- store at 25'C (77'F); excursions permitted between 15'-30'C (59'-86'F)

#### **Inactive Ingredients**

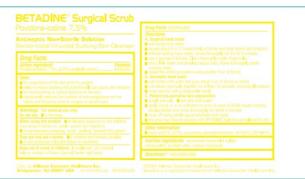
ammonium nonxynol-4 sulfate, nonoxynol-9, purified water, sodium hydroxide

#### Questions?

1-833-288-2684







# **BETADINE**

povidone-iodine liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0116-0151
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	0.075 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
AMMONIUM NONOXYNOL-4 SULFATE (UNII: 9HIA70O4J0)			
NONOXYNOL-9 (UNII: 48Q180SH9T)			
WATER (UNII: 059QF0KO0R)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116- 0151-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/07/2024	
2	NDC:0116- 0151-01	3780 mL in 1 BOTTLE, PLASTIC; 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(0116-0151)		

Revised: 11/2024 Xttrium Laboratories, Inc.