

BETADINE- povidone-iodine liquid
Xttrium Laboratories, Inc.

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 hands and forearms
- without adding more water, scrub thoroughly for 2 1/2 to 3 minutes
- use a sponge if desired. Clean thoroughly under fingernails.
- add a little water and develop copious suds. Rinse thoroughly under 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, covering all 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

NDC 67618-151-04 NSN 6505-00-491-7557
Not for Retail Sale For Professional and Hospital Use Only

BETADINE® Surgical Scrub


Povidone-iodine, 7.5%
Antiseptic Non-Sterile Scrub
 Bacterial/Virucidal Sudsing Skin Cleanser

<p>Drug Facts</p> <p>Active ingredient Povidone-iodine, 7.5% (0.75% available iodine) Antiseptic</p> <p>Uses</p> <ul style="list-style-type: none"> ■ 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 and forearms prior to surgery or patient care <p>Warnings For external use only Do not use ■ in the eyes</p> <p>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</p> <p>Stop use and ask a doctor ■ if irritation and redness develop ■ in rare instances of local irritation or sensitivity</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away ▶</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <p>A. Surgical hand scrub:</p> <ul style="list-style-type: none"> ■ wet hands with water ■ spread about 5 cc (1 teaspoonful) of Scrub over both hands and forearms ■ without adding more water, scrub thoroughly for 2½ to 3 minutes ■ use a sponge if desired. Clean thoroughly under fingernails. ■ add a little water and develop copious suds. Rinse thoroughly under running water. ■ repeat the entire procedure using another 5 cc of Scrub <p>B. Antiseptic hand wash:</p> <ul style="list-style-type: none"> ■ wet hands with water and pour about 5 cc of Scrub on hands ■ rub hands vigorously together for at least 15 seconds, covering all surfaces ■ rinse and dry with a disposable towel <p>C. Patient pre-operative skin preparation:</p> <ul style="list-style-type: none"> ■ 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 <p>Other information</p> <ul style="list-style-type: none"> ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) <p>Inactive ingredients ammonium nonxynol-4 sulfate, nonoxynol-9, purified water, sodium hydroxide</p> <p>Questions? 1-833-288-2684</p>
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4 fl oz (118 ml)

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





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	Basis of Strength	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: 9HIA7004J0)	
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	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-0151)

Revised: 11/2024

Xttrium Laboratories, Inc.