

BETADINE SURGICAL SCRUB- povidone-iodine solution
Atlantis Consumer Healthcare, Inc.

Betadine Surgical Scrub

Drug Facts

Active ingredient

Povidone-iodine, 7.5%(0.75% available iodine)

Purpose

Antiseptic

Uses

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

Warnings

For external use only

Do not use this product

- in the eyes

When using this product

- prolonged exposure to wet solution may cause irritation or, rarely, severe skin reactions

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 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

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C(59°-86°F)
- store in original container

Inactive ingredients

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

Dist. by:

AvrioHealth L.P. Stamford, CT 06901-3431

304954-0A

Betadine Surgical Scrub
NDC 67618-151-17

Not for Retail Sale

NDC 67818-151-17

For Professional and Hospital Use Only

BETADINE[®] Surgical Scrub

Povidone-iodine, 7.5%

Antiseptic Non-Sterile Scrub

Bactericidal/Virucidal Sudsing
Skin Cleanser

16 fl oz
(473 ml)



BETADINE SURGICAL SCRUB

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67618-151
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)		IODINE	.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:67618-151-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/1996	
2	NDC:67618-151-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/1996	01/31/2025
3	NDC:67618-151-17	1 in 1 CARTON	07/01/1996	01/31/2025
3		473 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:67618-151-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/1996	11/30/2024
5	NDC:67618-151-01	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/1996	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M003	07/01/1996	

Labeler - Atlantis Consumer Healthcare, Inc. (118983925)

Registrant - Atlantis Consumer Healthcare, Inc. (118983925)