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

XTT Betadine 10% Professional

Active Ingredient

Povidone-iodine, 10%

Purpose

Antiseptic

Uses

Patient pre-operative skin preparation

- for preparation of the skin prior to surgery
- helps reduce bacteria that potentially can cause skin infection

Warnings

For external use only

Do not use \blacksquare in the eyes \blacksquare if you are allergic to povidone-iodine or any other ingredients in this preparation

When using this product

■ prolonge 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, sensitization, or allergic reaction occurs and lasts for 72 hours. These may be signs of a serious condition.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- \blacksquare single use only \blacksquare clean the operative site prior to surgery
- \blacksquare apply product and allow to dry \blacksquare may be covered with a sterile bandage

Other information

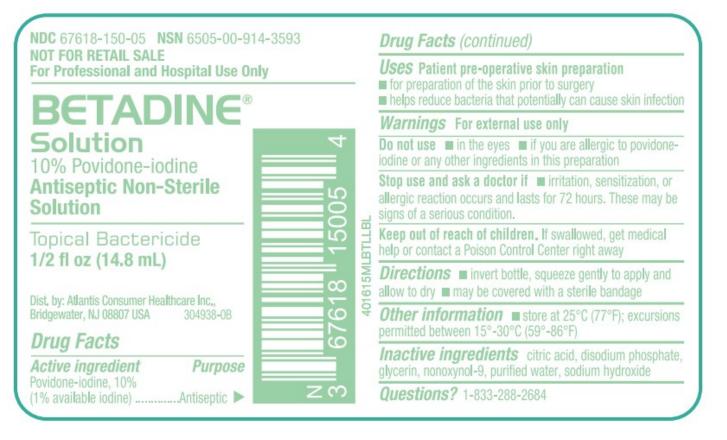
- store in original container
- store at 25'C (77'F); excursions permitted between 15'-30'C (59'-86'F)

Inactive Ingredient

citric acid, disodium phosphate, glycerin, nonoxynol-9, purified water, sodium hydroxide

Questions?

1-833-288-2684



Not for Retail Sale	Drug Facts (continued)
DC 67618-150-04 NSN 6505-01-067-2812 or Professional and Hospital Use Only	Uses Patient pre-operative skin preparation for preparation of the skin prior to surgery helps reduce bacteria that potentially can cause skin infection
BETADINE	Warnings For external use only
Solution	Do not use in the eyes if you are allergic to povidone-iodine or any other ingredients in this preparation
0% Povidone-iodine 🚃 🗋	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
Intiseptic Non-Sterile	Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs and lasts for 72 hours. These may be signs of a serious condition,
fl oz (118 mL)	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away
st. by: Atlantis Consumer Healthcare Inc.	Directions ■ single use only ■ clean the operative site prior to surgery ■ apply product and allow to dry ■ may be covered with a sterile bandage
M944-0A 4016048TLLEL 20	Other information ■ store in original container ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
Drug Facts Active ingredient Purpose	Inactive ingredients citric acid, disodium phosphate, glycerin, nonoxynoF9, purified water, sodium hydroxide
Povidone-iodine, 10% (1% available iodine)	Questions? 1-833-288-2684

Not for Retail Sale

NDC 67618-150-09 NSN 6505-00-286-7011 For Professional and Hospital Use Only

BETADINE® Solution

10% Povidone-iodine

Antiseptic Non-Sterile Solution

Topical Bactericide



Drug Facts

Active ingredient

Purpose

Povidone-iodine, 10% (1% available iodine).....Antiseptic

Uses

Patient pre-operative skin preparation ■ for preparation of the skin prior to surgery ■ helps reduce bacteria that potentially can cause skin infection

Warnings

For external use only

Do not use in the eyes if you are allergic to povidone-iodine or any other ingredients in this preparation

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, sensitization, or allergic reaction occurs and lasts for 72 hours. These may be signs of a serious condition.

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

Directions

■ single use only ■ clean the operative site prior to surgery ■ apply product and allow to dry ■ may be covered with a sterile bandage

Other information

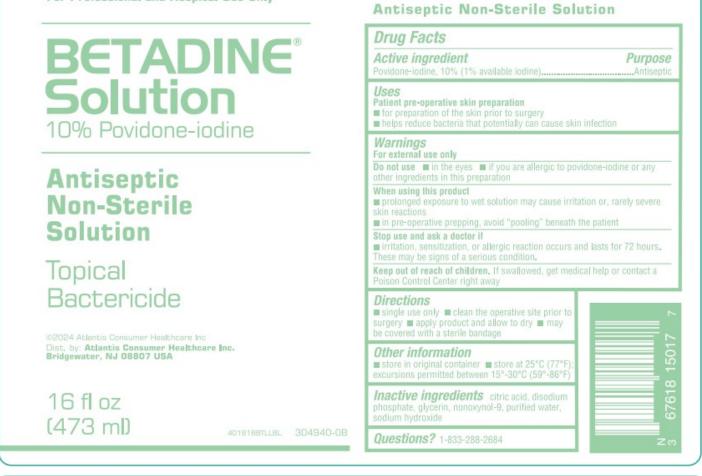
■ store in original container ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients citric acid, disodium phosphate, glycerin, nonoxynol-9, purified water, sodium hydroxide

Questions? 1-833-288-2684

Not for Retail Sale

NDC 67618-150-17 For Professional and Hospital Use Only



BETADINE[®]

10% Povidone-iodine

Solution



BETADINE			
10% povidone-iodine liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0116-0150
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL
Inactive Ingredients		
Ingredient Name		Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
NONOXYNOL-9 (UNII: 48Q180SH9T)		
SODIUM PHOSPHATE, DIBASIC, MONOHYDRATE (UNII: BWZ 7K44R51)		
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0KO0R)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116- 0150-05	14.8 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/05/2024	
2	NDC:0116- 0150-01	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/05/2024	
3	NDC:0116- 0150-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/05/2024	
4	NDC:0116- 0150-09	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/05/2024	
5	NDC:0116- 0150-17	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/05/2024	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M003	11/05/2024	

Labeler - Xttrium Laboratories, Inc. (007470579)

Registrant - Xttrium Laboratories, Inc. (007470579)

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

Revised: 11/2024

Xttrium Laboratories, Inc.