

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 ■ in the eyes ■ 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

- 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 Ingredient

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

Questions?

1-833-288-2684

NDC 67618-150-05 NSN 6505-00-914-3593
NOT FOR RETAIL SALE
For Professional and Hospital Use Only

BETADINE[®]

Solution

10% Povidone-iodine
Antiseptic Non-Sterile
Solution

Topical Bactericide
1/2 fl oz (14.8 mL)

Dist. by: Atlantis Consumer Healthcare Inc.,
Bridgewater, NJ 08807 USA 304938-0B

Drug Facts

Active ingredient	Purpose
Povidone-iodine, 10% (1% available iodine)	Antiseptic ▶



Drug Facts (continued)

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

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 ■ invert bottle, squeeze gently to apply and allow to dry ■ may be covered with a sterile bandage

Other information ■ 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 67618-150-04 NSN 6505-01-067-2812
For Professional and Hospital Use Only

BETADINE[®] Solution

10% Povidone-iodine
**Antiseptic Non-Sterile
Solution**
Topical Bactericide

4 fl oz (118 mL)

©2024 Atlantis Consumer Healthcare Inc
Dist. by: **Atlantis Consumer Healthcare Inc.**
Bridgewater, NJ 08807 USA
304944-0A 401604BTLBL



Drug Facts

Active ingredient	Purpose
Povidone-iodine, 10% (1% available iodine).....	Antiseptic ▶

Drug Facts (continued)

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

BETADINE[®] Solution

10% Povidone-iodine

**Antiseptic Non-Sterile
Solution**

Topical Bactericide

©2024 Atlantis Consumer Healthcare Inc
Dist. by: **Atlantis Consumer Healthcare Inc.**
Bridgewater, NJ 08807 USA
401608BTLBL 304948-0B



8 fl oz
(237 ml)

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® Solution

10% Povidone-iodine

Antiseptic Non-Sterile Solution

Topical Bactericide

©2024 Atlantis Consumer Healthcare Inc.
Dist. by: Atlantis Consumer Healthcare Inc.
Bridgewater, NJ 08807 USA

16 fl oz
(473 mL)

401616BTL16L 304940-0B

BETADINE® Solution

10% Povidone-iodine
Antiseptic Non-Sterile Solution

Drug Facts

Active ingredient Povidone-iodine, 10% (1% available iodine).....**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 ■ 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 67618-150-01
For Professional and Hospital Use Only

BETADINE® Solution

10% Povidone-iodine
Antiseptic Non-Sterile Solution
Topical Bactericide

©2024 Atlantis Consumer Healthcare Inc.
Dist. by: Atlantis Consumer Healthcare Inc.
Bridgewater, NJ 08807 USA



Not for Retail Sale
For Professional and Hospital Use Only

BETADINE® Solution

10% Povidone-iodine

Antiseptic Non-Sterile Solution

Topical Bactericide

One Gallon (3.78 Liters)

Drug Facts

Active ingredient Povidone-iodine, 10% (1% available iodine).....**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 ■ in the eyes ■ if you are allergic to povidone-iodine or any other ingredients in this preparation

When using this product

■ single use will reduce the risk of infection from extrinsic contamination
■ 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

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: BWZ7K44R51)				
GLYCERIN (UNII: PDC6A3C00X)				
WATER (UNII: 059QF0KO0R)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
Packaging				
#	Item 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 Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End 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.