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

BETADINE[®] Professional Solution Swabsticks Povidone-iodine 10%

Drug Facts

Active ingredient

Povidone-iodine 10%

Purpose

Antiseptic

Use(s)

- for preparation of the skin prior to surgery
- first aid to help prevent infection in minor cuts, scrapes, and burns

Warnings

For external use only

Do not use

- in the eyes or over large areas of the body
- longer than 1 week unless directed by a doctor
- if you are allergic to iodine or other product ingredients

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious wounds

When using this product

• prolonged exposure may cause irritation or, rarely, severe skin reactions

Stop use and ask a doctor

- if condition persists or gets worse
- 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 (1-800-222-1222) right away.

Directions

- tear at notch
- remove applicator
- use only once

As a first aid antiseptic:

- clean affected area
- apply 1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first

For preoperative patient skin preparation:

- clean area
- apply to operative site using applicator then wait at least 30 seconds prior to surgery

Other Information

- store at room temperature 15°-30°C (59°-86°F)
- avoid excessive heat

Inactive Ingredients

citric acid, glycerin, polysorbate 80 (tween 80), sodium citrate USP, sodium phosphate dibasic, water

Questions

1-833-288-2684

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

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PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 67618-190-01

BETADINE[®] SOLUTION Swabsticks Povidone-iodine 10% To Open Tear At Slit

Antiseptic Non-Sterile Solution

Contains 1 Single-Use, Disposable Swabstick

Do not use if package is damaged or open.

Not Labeled for Consumer Use

For Professional and Hospital Use Only

A1224

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See box for complete **Drug Facts**

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Drug Footo
Drug Facts
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Uses for preparation of the skin prior to surgery first aid to help prevent infection in minor cuts, scrapes, and burns
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When using this product prolonged exposure may cause irritation or, rarely, severe skin reactions
 Stop use and ask a doctor if condition persists or gets worse 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 (800-222-1 222) right away.
See box for complete Drug Facts.
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Questions?_1-833-288-2684_

NDC 67618-190-50

For Professional and Hospital Use Only

BETADINE[®] SOLUTION Swabsticks

Povidone-iodine 10%

Antiseptic Non-Sterile Solution

50

Single-use, Disposable Swabsticks 1 saturated swab per packet

LOT LLLLLLLLLL

EXP YYYY-MM-DD



NDC 67618-190-03

BETADINE[®] SOLUTION Swabsticks Povidone-iodine 10%

To Open Tear At Slit

Antiseptic Non-Sterile Solution

Contains 3 Single-Use, Disposable Swabstick

Do not use if package is damaged or open.

For Professional and Hospital Use Only

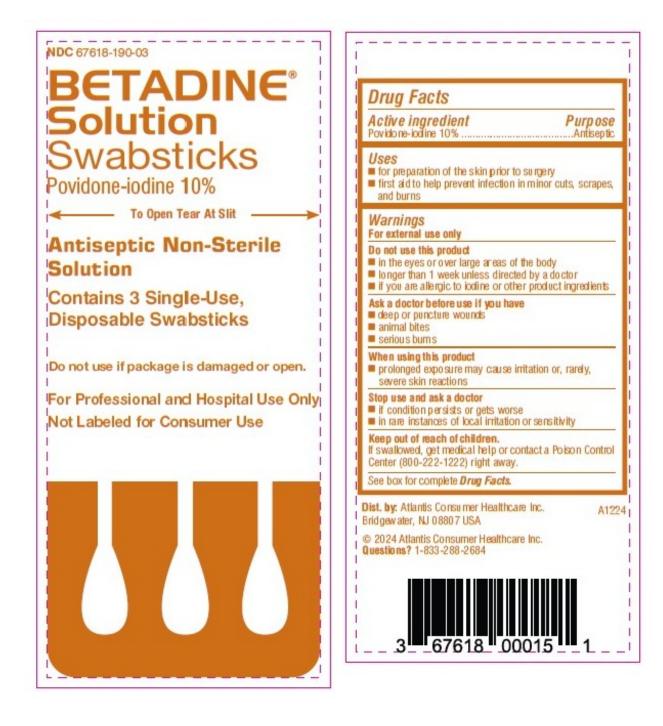
Not Labeled for Consumer Use

See box for complete **Drug Facts**

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NDC 67618-190-25

For Professional and Hospital Use Only

BETADINE[®] SOLUTION Swabsticks

Povidone-iodine 10%

Antiseptic Non-Sterile Solution

25

Single-use, Disposable Swabsticks 3 saturated swabs per packet

LOT LLLLLLLLLL

EXP YYYY-MM-DD



BETADINE									
povidone-iodine solution									
Product Information									
Product Type	HUMAN OTC DRUG	ltem Code	(Source)	NDC:6	7618-190				
Route of Administration	TOPICAL								
Active Ingredient/Active Moiety									
Ingredient Name			Basis of Streng	th	Strength				
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)			IODINE	10	0 mg in 1 mL				

Strength

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:67618- 190-01	1 in 1 POUCH	07/01/2025					
1		1.9 mL in 1 APPLICATOR; Type 0: Not a Combination Product						
2	NDC:67618- 190-03	3 in 1 POUCH	07/01/2025					
2		1.9 mL in 1 APPLICATOR; Type 0: Not a Combination Product						
3	NDC:67618- 190-50	50 in 1 BOX	07/01/2025					
3		1 in 1 PACKET						
3		1.9 mL in 1 APPLICATOR; Type 0: Not a Combination Product						
4	NDC:67618- 190-25	25 in 1 BOX	07/01/2025					
4		3 in 1 PACKET						
4		1.9 mL in 1 APPLICATOR; Type 0: Not a Combination Product						
Marketing Information								
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
ОТ	C Monograph Dr	rug M003	07/01/2025					

Labeler - Atlantis Consumer Healthcare, Inc. (118983925)

Registrant - Atlantis Consumer Healthcare, Inc. (118983925)

Revised: 2/2025

Atlantis Consumer Healthcare, Inc.