

**BETADINE SOLUTION SWABSTICKS- povidone-iodine swab
Purdue Products LP**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Betadine® Solution Swabsticks

Povidone-iodine Solution USP, 10 %

Drug Facts

Active Ingredient Purpose

Povidone-iodine Solution USP, 10% (equal to 1% available iodine)

Purpose

Antiseptic

Uses

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

Warnings

For external use only

Do not use this product

- in the eyes
- if you are allergic to iodine or other product ingredients

When using this product

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

Stop using this product

- in rare instances of local irritation or sensitivity
- if irritation and redness develop and continue for more than 72 hours

Keep out of reach of children

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

Directions

- tear at slit; pull top of packette across, exposing end of swabstick
- remove Betadine Solution Swabstick and apply as needed
- use one time only

Other information

- store between 20°-25°C (68°-77°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

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

Dist. by: **Purdue Products L.P. Stamford, CT 06901-3431**

L01119B 301880-0A

Betadine Solution Swabsticks

NDC 67618-153-01

NDC 67618-153-01

disposable

BETADINE[®] Solution Swabstick

Povidone-iodine Solution USP, 10%

← To Open Tear At Slit →

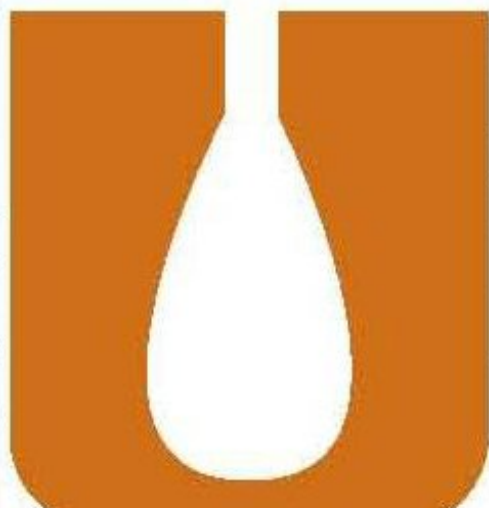
Contains 1 Swabstick

Do not use if package
is damaged or open.

Antiseptic Applicator Tip

Not for Retail Sale
Not Labeled for
Consumer Use
For Professional and
Hospital Use Only

Dist by
Purdue Products L.P.
Stamford, CT
06901-3431
L01117B 301879-0A



Drug Facts

Active ingredient Purpose

Povidone-iodine Solution
USP, 10% (equal to
1% available iodine) Antiseptic

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

Warnings

For external use only

Do not use this product ■ in the eyes
■ if you are allergic to iodine or
other product ingredients

When using this product

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

Stop using this product

■ in rare instances of local irritation
or sensitivity
■ if irritation and redness develop
and continue for more than
72 hours

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

Directions

■ tear at slit, pull top of packette
across, exposing end of swabstick
■ remove Betadine Solution
Swabstick and apply as needed
■ use one time only

Other information

■ store between 20°-25°C (68°-
77°F). Avoid freezing and excessive
heat above 40°C (104°F).

Inactive ingredients

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

Questions? 1-888-726-7535
(8am-5pm, EST, Mon-Fri.)

Betadine Solution Swabsticks
NDC 67618-153-03

NDC 67618-153-03 NSN 6510-01-008-7917

disposable

BETADINE® Solution Swabsticks

← To Open Tear At Slit →

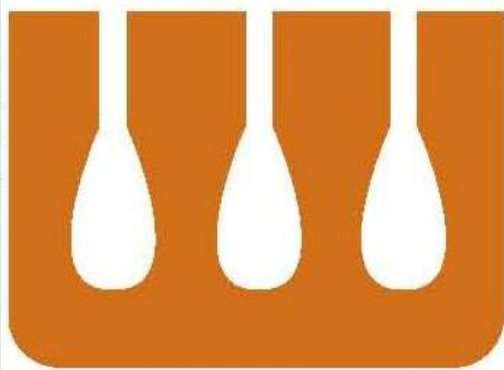
Povidone-iodine Solution
USP, 10%

Contains 3 Swabsticks

Do not use if package is
damaged or open.

**Antiseptic
Applicator Tip**

Not for Retail Sale
For Professional and
Hospital Use Only
Not Labeled for
Consumer Use



Drug Facts

Active ingredient	Purpose
Povidone-iodine Solution USP, 10% (equal to 1% available iodine)	Antiseptic

Uses

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

Warnings

For external use only

Do not use this product ■ in the eyes.
■ if you are allergic to iodine or other product ingredients

When using this product

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

Stop using this product

- in rare instances of local irritation or sensitivity
- if irritation and redness develop and continue for more than 72 hours

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

Directions

- tear at slit, pull top of packette across, exposing end of swabstick
- remove Betadine Solution Swabstick and apply as needed
- use one time only

Other information ■ store between 20° -25°C (68° -77°F). Avoid freezing and excessive heat above 40°C (104°F)

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

Questions? 1-888-726-7535 (8am-5pm, EST, Mon.-Fri.)

Dist by: **Purdue Products L.P.**
Stamford, CT 06901-3431
L01119B 301880-0A

BETADINE SOLUTION SWABSTICKS

povidone-iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67618-153
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (POVIDONE-IODINE - UNII:85H0HZU99M)	POVIDONE-IODINE	.01 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 9425516E2T)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0K00R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67618-153-01	1 in 1 PACKET		
2	NDC:67618-153-03	3 in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/15/1972	

Labeler - Purdue Products LP (141916531)**Registrant** - Purdue Products LP (141916531)**Establishment**

Name	Address	ID/FEI	Business Operations
Aplicare Inc.		107255002	MANUFACTURE