

POVIDONE-IODINE- povidone-iodine swab
Mazza Healthcare, LLC

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.

Drug Facts

Active ingredient

Povidone-Iodine, USP, 10% v/v
(equivalent to 1% titratable iodine)

Purpose

Antiseptic

Uses

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

Warnings

For external use only

Do not use

- in the eyes
- on individuals who are allergic or sensitive to iodine
- over large areas of the body
- as first aid antiseptic longer than 1 week unless directed by doctor

Discontinue use if irritation and redness develop.

Ask a doctor before use if you have deep or puncture wounds, animal bites or serious burns.

Stop use and consult a doctor if the condition persists or gets worse.

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

Directions

- clean the affected area
- for preparation of the skin prior to surgery, apply product to the operative site
- apply product on the area 1-3 times daily. May be covered with a sterile bandage. If

bandaged, let dry first.

Other information

Store at room temperature 59-86°F (15-30°C).

Inactive ingredients

citric acid, glycerin, Nonoxynol-10, purified water, sodium hydroxide

Mazza Healthcare, LLC
1-877-629-9242

Principal Display Panel - 500 Pouch Carton Label

MH

Mazza Healthcare

MODEL NO.: 02-053-00

DESCRIPTION: POVIDONE-IODINE SWABSTICKS, 4" SATURATED, NON-STERILE

QUANTITY: 1 CASE (500 POUCHES X 3 EACH)

LOT NO.:

MANUFACTURE DATE:

EXPIRY DATE:

MANUFACTURED FOR:

Mazza Healthcare, LLC

Bannockburn, IL 60015 • USA

MADE IN CHINA

NDC 81280-003-03



Principal Display Panel - 3 Applicators Pouch Label

MH

Mazza Healthcare

Povidone-Iodine Swabsticks

NDC 81280-003-03

Antiseptic • Germicide • 4" Saturated

Non-Sterile • Single Use Only

3/pouch

Reorder Number 02-053-00



Povidone-Iodine Swabsticks

NDC 81280-003-03

Antiseptic • Germicide
4" Saturated • Non-Sterile
Single Use Only

3/pouch

Reorder Number 02-053-00

Drug Facts

Active ingredient

Povidone-iodine, USP, 10% w/v
(equivalent to 1% titratable iodine)..... Antiseptic

Purpose

Uses ■ health care antiseptic for preparation of the skin prior to surgery ■ first aid antiseptic to help prevent the risk of skin infection in minor cuts, scrapes and burns

Warnings For external use only

Do not use ■ in the eyes ■ on individuals who are allergic or sensitive to iodine ■ over large areas of the body ■ as first aid antiseptic longer than 1 week unless directed by doctor

Discontinue use if irritation and redness develop.

Ask a doctor before use if you have deep or puncture wounds, animal bites or serious burns.

Drug Facts (continued)

Stop use and consult a doctor if the condition persists or gets worse.

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

Directions ■ clean the affected area ■ for preparation of the skin prior to surgery, apply product to the operative site ■ for use as a first aid antiseptic, apply a small amount of product to the area 1-3 times daily. May be covered with a sterile bandage. If bandaged, let dry first.

Other information

Store at room temperature 59-86°F (15-30°C).

Inactive ingredients citric acid, glycerin, Nonoxynol-10, purified water, sodium hydroxide

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Made in China #901-02-053-00 Rev. 0



LOT



Principal Display Panel - 500 Pouch Carton Label

MH

Mazza Healthcare

MODEL NO.: 02-051-00

DESCRIPTION: POVIDONE-IODINE SWABSTICKS, 4" SATURATED, NON-STERILE

QUANTITY: 1 CASE (500 POUCHES X 1 EACH)

LOT NO.:

MANUFACTURE DATE:

EXPIRY DATE:

MANUFACTURED FOR:

Mazza Healthcare, LLC

Bannockburn, IL 60015 • USA

MADE IN CHINA

NDC 81280-003-01



Principal Display Panel - 1 Applicator Pouch Label

MH

Mazza Healthcare

Povidone-Iodine Swabstick

NDC 81280-003-01

Antiseptic • Germicide • 4" Saturated

Non-Sterile • Single Use Only

1/pouch

Reorder Number 02-051-00



Povidone-Iodine Swabstick

NDC 81280-003-01

1/pouch

Antiseptic • Germicide • 4" Saturated
Non-Sterile • Single Use Only

Reorder Number 02-051-00

Drug Facts		Drug Facts (continued)
Active ingredient Povidone-iodine, USP, 10% w/v (equivalent to 1% titratable iodine).....	Purpose Antiseptic	Stop use and consult a doctor if the condition persists or gets worse.
Uses ■ health care antiseptic for preparation of the skin prior to surgery ■ first aid antiseptic to help prevent the risk of skin infection in minor cuts, scrapes and burns		Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
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POVIDONE-IODINE

povidone-iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81280-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Povidone-Iodine (UNII: 85H0HZU99M) (Iodine - UNII:9679TC07X4)	Iodine	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Glycerin (UNII: PDC6A3C0OX)	
Nonoxynol-10 (UNII: K7O76887AP)	
Water (UNII: 059QF0K00R)	
Sodium Hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81280-003-01	500 in 1 CARTON	03/01/2021	
1		1 in 1 POUCH		
1		2.5 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:81280-003-03	500 in 1 CARTON	03/01/2021	
2		3 in 1 POUCH		
2		4.5 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
OTC monograph final	part333C	03/01/2021	

Labeler - Mazza Healthcare, LLC (830069063)

Revised: 2/2021

Mazza Healthcare, LLC