

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

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
- 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

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

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Povidone-Iodine, USP, 10% w/v
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Drug Facts (continued)

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

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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.

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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

 <p>MODEL NO.: 02-051-00 DESCRIPTION: POVIDONE-IODINE SWABSTICKS, 4" SATURATED, NON-STERILE QUANTITY: 1 CASE (500 POUCHES X 1 EACH)</p> <p>LOT NO.: MANUFACTURE DATE: EXPIRY DATE:</p>	<p>MANUFACTURED FOR: Mazza Healthcare, LLC Bannockburn, IL 60015 • USA MADE IN CHINA</p> <p>NDC 81280-003-01</p>  <p>(01) 1 0850018 32782 1</p>	 <p>MODEL NO.: 02-051-00 DESCRIPTION: POVIDONE-IODINE SWABSTICKS, 4" SATURATED, NON-STERILE QUANTITY: 1 CASE (500 POUCHES X 1 EACH)</p> <p>MADE IN CHINA STORAGE: Store in a cool, dry place. Avoid direct sunlight. #910-02-051-00 Rev. 0</p>
 <p>MODEL NO.: 02-051-00 DESCRIPTION: POVIDONE-IODINE SWABSTICKS, 4" SATURATED, NON-STERILE QUANTITY: 1 CASE (500 POUCHES X 1 EACH)</p> <p>LOT NO.: MANUFACTURE DATE: EXPIRY DATE:</p>	<p>MANUFACTURED FOR: Mazza Healthcare, LLC Bannockburn, IL 60015 • USA MADE IN CHINA</p> <p>NDC 81280-003-01</p>  <p>(01) 1 0850018 32782 1</p>	 <p>MODEL NO.: 02-051-00 DESCRIPTION: POVIDONE-IODINE SWABSTICKS, 4" SATURATED, NON-STERILE QUANTITY: 1 CASE (500 POUCHES X 1 EACH)</p> <p>MADE IN CHINA STORAGE: Store in a cool, dry place. Avoid direct sunlight. #910-02-051-00 Rev. 0</p>

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

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. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
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		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.
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Ask a doctor before use if you have deep or puncture wounds, animal bites or serious burns. ▶		Inactive ingredients citric acid, glycerin, Nonoxynol-10, purified water, sodium hydroxide

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Made in China #901-02-051-00 Rev. 0

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: 059QF0KO0R)	
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 Drug	M005	03/01/2021	

Labeler - Mazza Healthcare, LLC (830069063)

Revised: 11/2024

Mazza Healthcare, LLC