

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

Use

- 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
- apply product on the area 1-3 times daily
- may be covered with a sterile bandage when dry

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 - 2000 Pouch Carton Label**MH**

Mazza Healthcare

MODEL NO.: 02-050-00

**DESCRIPTION: POVIDONE-IODINE PREP PADS, MEDIUM
NON-STERILE**

QUANTITY: 1 CASE (2000 EACH)

LOT NO.:

MANUFACTURE DATE:

EXPIRY DATE:

MANUFACTURED FOR:

Mazza Healthcare, LLC

Bannockburn, IL 60015 • USA

MADE IN CHINA

NDC 81280-002-01



MODEL NO.: 02-050-00
DESCRIPTION: POVIDONE-IODINE PREP PADS, MEDIUM
NON-STERILE
QUANTITY: 1 CASE (2000 EACH)
LOT NO.:
MANUFACTURE DATE:
EXPIRY DATE:

MANUFACTURED FOR:
Mazza Healthcare, LLC
Barrington, IL 60015 • USA
MADE IN CHINA

NDC 81280-002-01



(01) 1 0850018 32781 4



MODEL NO.: 02-050-00
DESCRIPTION: POVIDONE-IODINE PREP PADS, MEDIUM
NON-STERILE
QUANTITY: 1 CASE (2000 EACH)

MADE IN CHINA
STORAGE: Store at room temperature. Avoid excessive heat.
#910-02-050-00 Rev. 0



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DESCRIPTION: POVIDONE-IODINE PREP PADS, MEDIUM
NON-STERILE
QUANTITY: 1 CASE (2000 EACH)
LOT NO.:
MANUFACTURE DATE:
EXPIRY DATE:

MANUFACTURED FOR:
Mazza Healthcare, LLC
Barrington, IL 60015 • USA
MADE IN CHINA

NDC 81280-002-01



(01) 1 0850018 32781 4



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Principal Display Panel - 1 Prep Pad Pouch Label

MH

Mazza Healthcare

**Povidone-Iodine
Prep Pad**

NDC 81280-002-01

Antiseptic • Germicide

Medium • 2-Ply

Non-Sterile • Single Use Only

Reorder No. 02-050-00



Povidone-Iodine Prep Pad

NDC 81280-002-01

**Antiseptic • Germicide
Medium • 2-Ply
Non-Sterile • Single Use Only**

Reorder No. 02-050-00

Drug Facts

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LOT



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Drug Facts (continued)

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POVIDONE-IODINE

povidone-iodine swab

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:81280-002

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: PDC6A3C00X)	
Nonoxynol-10 (UNII: K7O76887AP)	
Water (UNII: 059QF0K00R)	
Sodium Hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81280-002-01	2000 in 1 CARTON	03/01/2021	
1		1 in 1 POUCH		
1		0.34 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