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

МН

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

МН

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



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



MODEL NO .:

02-051-00

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

QUANTITY: 1 CASE (500 POUCHES X 1 EACH)







MODEL NO .: 02-051-00

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

QUANTITY: 1 CASE (500 POUCHES X 1 EACH)

MADE IN CHINA STORAGE: Stare in a cool, dry place. Avoid direct surlight. #910-02-051-90 Rev. 0



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

QUANTITY: 1 CASE (500 POUCHES X 1 EACH)







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

QUANTITY: 1 CASE (500 POUCHES X 1 EACH)

MADE IN CHENA STORAGE: Store in a cool, dry place. Availd direct sanlight. #910-00-051-00 Rev. D

Principal Display Panel - 1 Applicator Pouch Label MH

Mazza Healthcare

Povidone-Iodine Swabstick

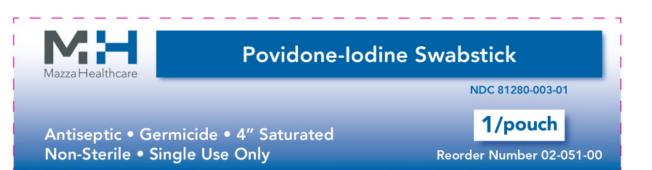
NDC 81280-003-01

Antiseptic • Germicide • 4" Saturated

Non-Sterile • Single Use Only

1/pouch

Reorder Number 02-051-00





POVIDONE-IODINE

povidone-iodine swab

Product	Intorm	ation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81280-003

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Povidone-Iodine (UNII: 85H0HZ U99M) (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 final	part333C	03/01/2021		

Labeler - Mazza Healthcare, LLC (830069063)

Revised: 2/2021 Mazza Healthcare, LLC