

3M SKIN AND NASAL ANTISEPTIC- povidone-iodine solution

3M Health Care

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.

3M™ Skin and Nasal Antiseptic

(Povidone-Iodine Solution 5% w/w (0.5% available iodine) USP)

Patient Preoperative Skin Preparation

Drug Facts

Active Ingredient

Povidone-Iodine USP, 5%
(0.5% Available Iodine)

Purpose

Antiseptic

Uses

- For preparation of the skin prior to surgery
- Helps reduce bacteria that potentially can cause skin infections

Warnings

For external use only.

Do not use if you have a known sensitivity to iodine or any other ingredient in this product. Do not use in eyes. If product gets into eyes, flush immediately with water. Do not use on infants less than 2 months old due to the risk of increased blood iodine levels.

Stop use and ask a doctor if significant irritation, sensitization or other allergic reactions occur.

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

Directions

- Open package and remove bottle and swabs
- Unscrew cap by turning cap counter-clockwise

Skin Application:

1. Apply to clean dry skin.
2. Dip one swab into solution and stir vigorously for 10 seconds. Withdraw the swab slowly to avoid wiping solution off during removal.
3. Scrub prep site for 2 minutes working from clean to dirty using both sides of the swab.
4. Repeat steps 2 & 3 using second swab.
5. Allow prep solution to dry. Do not blot.

Nasal Application:

1. Use a tissue to clean the inside of both nostrils including the inside tip of nostril. Discard.
2. Tilting the bottle slightly, dip one swab into solution and stir vigorously for 10 seconds. Withdraw

the swab slowly to avoid wiping solution off during removal.



1. Insert swab comfortably into one nostril and rotate for 15 seconds covering all surfaces. Then focus on the inside tip of nostril and rotate for an additional 15 seconds. (swab 1)



1. Using a new swab: Repeat steps 2 & 3 with the other nostril. (swab 2)
2. Repeat the application in both nostrils using a fresh swab each time. (swabs 3 & 4)



1. Do not blow nose. If solution drips out of nose, it can be lightly dabbed with at tissue.

Other information

store at 20-25°C (68-77°F)

Inactive Ingredients:

lactic acid, lauramidopropylamine oxide, malic acid, polyquarternium-10, PPG-5-ceteth-10 phosphate, sodium hydroxide, sodium iodide, steareth-100, water, xylitol

Questions?

Call 1 800-228-3957 (Monday to Friday 7 am to 6 pm CST) www.3M.com

Patent No. 3M.com/Patents

Made in U.S.A. by **3M Health Care**

2510 Conway Ave., St. Paul, MN 55144

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34-8721-1989-5

Principal Display Panel – Carton

3M Skin and Nasal Antiseptic

(Povidone-Iodine Solution 5% w/w (0.5% available iodine) USP)

Patient Preoperative Skin Preparation

Non-Sterile Solution

Contents:

12 pouches

Each Pouch Contains:

- 1 Bottle 0.14 fl oz (4 mL)
- 4 Sterile Swabs

Applicators Are Sterile If Swab Pouch Is Intact

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St. Paul, MN 55144

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Skin and Nasal Antiseptic

Skin and Nasal Antiseptic
(Povidone-Iodine Solution 5%
w/w (0.5% available iodine) USP)

Patient Preoperative
Skin Preparation
Non-Sterile Solution



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Skin and Nasal Antiseptic

(Povidone-Iodine Solution 5% w/w (0.5% available iodine) USP)

Patient Preoperative Skin Preparation Non-Sterile Solution

<p>Drug Facts</p> <p>Active Ingredient Povidone-iodine USP 5% (0.5% Available Iodine)</p> <p>Purpose Antiseptic</p> <p>Uses</p> <ul style="list-style-type: none"> • For preparation of the skin prior to surgery • Helps reduce bacteria that potentially can cause skin infections <p>Warnings</p> <p>For external use only.</p> <p>Do not use if you have a known sensitivity to iodine or any other ingredient in this product. Do not use in eyes. If product gets into eyes, flush immediately with water. Do not use on infants less than 2 months old due to the risk of increased blood iodine levels.</p> <p>Stop use and ask a doctor if significant irritation, sensitization or other allergic reactions occur.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> • Open package and remove bottle and swabs • Unscrew cap by turning cap counter-clockwise • Apply to clean dry skin • Dip one swab into solution and stir vigorously for 10 seconds. Withdraw the swab slowly to avoid wiping solution off during removal. • Scrub prep site for 2 minutes working from clean to dirty using both sides • Repeat steps 2 & 3 using second swab. • Allow prep solution to dry. Do not blot. <p>Nasal Applications:</p> <ol style="list-style-type: none"> 1. Use steps 1 to open the inside of both nostrils including the inside lip 2. Tilt the bottle slightly, dip one swab into solution and stir vigorously for 10 seconds. Withdraw the swab slowly to avoid wiping solution off during removal. 3. Insert swab into one nostril and rotate for 15 seconds covering all surfaces. Then focus on the inside lip of nostril and rotate for an additional 15 seconds. (swab 1) 4. Using a new swab: Repeat steps 2 & 3 with the other nostril. (swab 2) 5. Repeat the application in both nostrils using a fresh swab each time. 6. Do not blow nose. If solution drips out of nose, it can be lightly dabbed with a tissue. 	 <p>Other Information • Store at 20-25°C (68-77°F).</p> <p>Contains: Povidone-iodine, hydroxyethylamine oxide, malic acid, polyacrylamide-10, PPG-5-ethers-10 phosphate, sodium hydroxide, sodium iodide, steareth-100, water, xylitol</p> <p>Questions? Call 1-800-228-3957 (Monday to Friday 7 am to 6 pm CST) www.3M.com</p>
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Skin and Nasal Antiseptic

Skin and Nasal Antiseptic
(Povidone-Iodine Solution 5%
w/w (0.5% available iodine) USP)

Patient Preoperative
Skin Preparation
Non-Sterile Solution



Principal Display Panel – Pouch Label
NDC 17518-060-04
Not Made With Natural Rubber Latex

Do Not Reuse

3M Skin and Nasal Antiseptic

Skin and Nasal Antiseptic

(Povidone-Iodine Solution 5% w/w (0.5% available iodine) USP)

Patient Preoperative

Skin Preparation

Non-Sterile Solution

Each Pouch Contains:

- 1 Bottle 0.14 fl oz (4 mL)
- 4 Sterile Swabs

Applicators are sterile if swab pouch is intact

REF

192401

3M™ Skin and Nasal Antiseptic
(Povidone-Iodine Solution 5% w/w
(0.5% available iodine) USP)
Patient Preoperative Skin Preparation
Non-Sterile Solution

Drug Facts

Active Ingredient	Purpose
Povidone-Iodine USP, 5%Antiseptic (0.5% Available Iodine)	

Uses

- For preparation of the skin prior to surgery
- Helps reduce bacteria that potentially can cause skin infections

Warnings
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Nasal Application:

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5. Repeat the application in both nostrils using a fresh swab each time. (swabs 3 & 4)
6. Do not blow nose, if solution drips out of nose, it can be lightly dabbed with a tissue.



Other information store at 20-25°C (68-77°F)

Inactive Ingredients: lactic acid, lauramidopropylamine oxide, malic acid, polyquarternium-10, PPG-5-ceteth-10 phosphate, sodium hydroxide, sodium iodide, steareth-100, water, xylitol

Questions?
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EXP YYYY-MM-DD
(WHITE MATERIAL)

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NDC# 17518-060-04



Skin and Nasal Antiseptic

Skin and Nasal Antiseptic
(Povidone-Iodine Solution 5% w/w
(0.5% available iodine) USP)

Patient Preoperative
Skin Preparation
Non-Sterile Solution



Each Pouch Contains:
1 Bottle 0.14 fl oz (4 mL)
4 Sterile Swabs
Applicators are sterile
if swab pouch is intact

REF
192401

3M SKIN AND NASAL ANTISEPTIC

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17518-060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Povidone-Iodine (UNII: 85H0HZU99M) (Iodine - UNII:9679TC07X4)	Iodine	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
lactic acid (UNII: 33X04XA5AT)	
malic acid (UNII: 817L1N4CKP)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium iodide (UNII: F5WR8N145C)	
steareth-100 (UNII: 4OH5W9UMB7)	
water (UNII: 059QF0KO0R)	
xylitol (UNII: VCQ006KQ1E)	
Lauramidopropylamine Oxide (UNII: I6KX160QTV)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17518-060-04	12 in 1 CARTON	07/01/2009	
1		1 in 1 POUCH		
1		4 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/01/2009	

Labeler - 3M Health Care (006173082)

Establishment

Name	Address	ID/FEI	Business Operations
3M Company		054950670	analysis(17518-060) , label(17518-060) , manufacture(17518-060) , pack(17518-060)

Establishment

Name	Address	ID/FEI	Business Operations
3M Company		830016148	analysis(17518-060)

Establishment

Name	Address	ID/FEI	Business Operations
BASF		040776809	api manufacture(17518-060)

Establishment

Name	Address	ID/FEI	Business Operations
Pace Analytical Life Sciences, LLC		797903197	analysis(17518-060)

Revised: 6/2019

3M Health Care