3M SKIN AND NASAL ANTISEPTIC- povidone-iodine solution Solventum US OpCo LLC

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:

- 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.



3. 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)



- 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. (swabs 3 & 4)
- 6. 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:

ceteareth-25, lactic acid, lauramidopropylamine oxide, malic acid, polyquarternium-10, PPG-5-ceteth-10 phosphate, sodium hydroxide, sodium iodide, water, xylitol

Questions?

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

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

Made in U.S.A. by

3M Health Care

2510 Conway Ave.

St. Paul, MN 55144

3M is a trademark of 3M

1-800-228-3957

3m.com/Medical

3M is a trademark of 3M

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34-8726-9172-9



Principal Display Panel - Pouch Label

NDC 17518-060-04

Not Made With Natural Rubber Latex

Do Not Reuse

3M Skin and Nasal Antiseptic

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REF

192401

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Inactive Ingredients: ceteareth-25, lactic acid, lauramidopropylamine oxide, malic acid, polyquarternium-10, PPG-5-ceteth-10 phosphate, sodium hydroxide, sodium iodide, water, xylitol

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Patent: 3M.com/Patents Made in U.S.A. by ■3M Health Care 2510 Conway Ave. St. Paul, MN 55144 3M is a trademark of 3M. © 2021, 3M. All rights reserved. 34-8726-9171-1

LOT: CODE EXP YYYY-MM-DD (WHITE MATERIAL) Tear Here

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



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(WHITE MATERIAL)

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)	lodine	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)				
ceteareth-25 (UNII: 8FA93U5T67)				
Water (UNII: 059QF0KO0R)				
Xylitol (UNII: VCQ006KQ1E)				
Lauramidopropylamine Oxide (UNII: I6KX160QTV)				

P	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 Drug	M003	07/01/2009		

Labeler - Solventum US OpCo LLC (006173082)

Establis	shmen	t	
Name	Address	ID/FEI	Business Operations
3M Company		054950670	ANALYSIS(17518-060), LABEL(17518-060), MANUFACTURE(17518-060), PACK(17518-060)

Establishn	nent		
Name	Address	ID/FEI	Business Operations
3M Company		078671244	MANUFACTURE(17518-060), ANALYSIS(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: 4/2024 Solventum US OpCo LLC