

3M SKIN AND NASAL ANTISEPTIC- povidone-iodine solution

3M Company

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.



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 a tissue.

Other information

store at 20-25°C (68-77°F)

Inactive Ingredients:

cetareth-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

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

Uses

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

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Questions?

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(01) 0 07 07387 78527 7

Patent: 3M.com/Patents
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LOT: CODE
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EXP YYYY-MM-DD
(WHITE MATERIAL)

Tear Here

NDC# 17518-060-04



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

(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) | 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) | |
| cetareth-25 (UNII: 8FA93U5T67) | |
| 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 Company (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 | | 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: 11/2022

3M Company