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.

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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

Made in U.S.A. by 3M Health Care
2510 Conway Ave., St. Paul, MN 55144

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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
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
## Drug Facts

**Active Ingredient**
- Povidone-Iodine Solution 5% (0.5% available iodine) USP

**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 in 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 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 losing solution 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 lip of nostril. Discard.
2. Tilt the bottle slightly, dip one swab into solution and stir vigorously for 10 seconds. Withdraw the swab slowly to avoid losing solution during removal.
3. Insert swab comfortably 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 the 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**
- Lactic acid, l-arginine, lecithin, sodium hydroxide, disodium edetate, polyethylene glycol 300, propylene glycol 65%, propylene glycol 10% solution, sodium hydroxide, sodium hydroxide, water, xanthan gum.

**Questions?**
- Call 1 800-229-4867 (Monday to Friday 7 am to 6 pm CST) www.3M.com

Patent: 3M.com/Patents
Made in U.S.A. by 3M Health Care
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34-8721-1989-5

**Lot Code:**
0000000000
EXP YYYY-MM-DD
(WHITE MATERIAL)

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### Tear Here

**NDC# 17518-060-04**

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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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**Each Pouch Contains:**
1 Bottle 0.14 fl oz (4 mL)
4 Sterile Swabs
Applicators are sterile if swab pouch is intact
# 3M SKIN AND NASAL ANTISEPTIC

**povidone-iodine solution**

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
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<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
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<table>
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<tr>
<th>Route of Administration</th>
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<tbody>
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## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>Povidone-Iodine (UNII: 85H0HZU99M) (Iodine - UNII:9679TC07X4)</td>
<td>Iodine</td>
<td>5 mg in 1 mL</td>
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## Inactive Ingredients

<table>
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<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>Lactic acid (UNII: 33X04XA5AT)</td>
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<td>Malic acid (UNII: 817L1N4CKP)</td>
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<td>Sodium hydroxide (UNII: 55X04QC32I)</td>
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<tr>
<td>Sodium iodide (UNII: F5WR8N145C)</td>
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<td>Steareth-100 (UNII: 4OH5W9UM87)</td>
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<td>Water (UNII: 059QF0K00R)</td>
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<td>Xylitol (UNII: VCQ006KQ1E)</td>
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<td>Lauramidopropylamine Oxide (UNII: 16KX160QTV)</td>
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## Packaging

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<td>12 in 1 CARTON</td>
<td>07/01/2009</td>
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<td>1</td>
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<td>1 in 1 POUCH</td>
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<tr>
<td>1</td>
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<td>4 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
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## Marketing Information

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<th>Application Number or Monograph Citation</th>
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<tr>
<td>OTC monograph not final</td>
<td>part333E</td>
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## Labeler

- 3M Health Care (006173082)

## Establishment

<table>
<thead>
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<th>Business Operations</th>
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<tbody>
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<td>analysis(17518-060) , label(17518-060) , manufacture(17518-060) , pack(17518-060)</td>
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