

**SKIN ANTISEPSIS, ORAL CLEANSING, NASAL ANTISEPSIS- chlorhexidine gluconate  
Sage Products, Inc.**

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**2% Chlorhexidine Gluconate Cloth and 3M Skin and Nasal Antiseptic**

**Active ingredient**

chlorhexidine gluconate 2% solution

Povidone-Iodine USP, 5%

**Purpose**

Antiseptic

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**Uses**

- helps reduce bacteria that can potentially cause skin infection
- for preparation of skin prior to surgery

**Warnings**

For external use only

**Do not use**

- on patients with known allergies to chlorhexidine gluconate or any other ingredients in this product
- for lumbar punctures or in contact with the meninges
- on open skin wounds or as a general skin cleanser

**When using this product**

- keep out of eyes, ears, and mouth. May cause serious or permanent injury if chlorhexidine is permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

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 irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition.

**Directions**

**2% Chlorhexidine Gluconate Cloth**

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- do not microwave

- product and packaging are not sterile. Follow your hospital policy for skin preparation with non-sterile products.

To open package

- holding top of package in one hand, lift flap on backside of package with other hand
- grasp flap at top and pull down to tear flap away and expose foam
- hold outside of package to present foam and cloths to prep table, avoiding contact between cloths and outside of package to reduce risk of cloth contamination.

Or

- using sterile scissors, cut off end seal of package
- transfer contents onto prep table, avoiding contact between cloths and outside of package to reduce risk of cloth contamination
- use first cloth to prepare the skin area indicated for a moist or dry site, making certain to keep the second cloth where it will not be contaminated. Use second cloth to prepare larger areas.
- dry surgical sites (such as abdomen or arm): use one cloth to cleanse each 161 cm<sup>2</sup> area (approximately 5 x 5 inches) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to air dry for one (1) minute. Do not rinse.
- moist surgical sites (such as inguinal fold): use one cloth to cleanse each 65 cm<sup>2</sup> area (approximately 2 x 5 inches) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to air dry for one (1) minute. Do not rinse.
- discard each cloth after a single use
- after package has been opened discard any unused cloths

## **Directions**

### **3M Skin and Nasal Antiseptic**

- 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.

## **Inactive ingredients**

### **2% Chlorhexidine Gluconate Cloth**

aloe vera, dimethicone, fragrance, glucono-delta-lactone, glycerin, Igepal, polysorbate 20, propylene glycol, USP purified water

cloth: polyester

### Inactive ingredients

### 3M Skin and Nasal Antiseptic

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

2% Chlorhexidine Gluconate\* Cloth

NDC 053462-705-23

**TO OPEN: Lift Flap and Tear at End**

**Drug Facts (continued)**

- transfer contents onto prep table, avoiding contact between cloths and outside of package to reduce risk of cloth contamination
- use first cloth to prepare the skin area indicated for a moist or dry site, making certain to keep the second cloth where it will not be contaminated. Use second cloth to prepare larger areas.
- **dry surgical sites** (such as abdomen or arm): use one cloth to cleanse each 161 cm<sup>2</sup> area (approximately 5 x 5 inches) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to air dry for one (1) minute. Do not rinse.
- **moist surgical sites** (such as inguinal fold): use one cloth to cleanse each 65 cm<sup>2</sup> area (approximately 2 x 5 inches) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to air dry for one (1) minute. Do not rinse.
- discard each cloth after a single use
- after package has been opened discard any unused cloths

**Other information**

- store product flat
- store between 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

**Inactive ingredients**

aloe vera, dimethicone, fragrance, glucono-delta-lactone, glycerin, Igepal®, polysorbate 20, propylene glycol, USP purified water  
cloth: polyester

**Questions or comments?**  
call toll-free 800-323-2220  
(Monday to Friday 8 AM-5 PM CST)  
www.sageproducts.com

**Reorder #9707**

6 18029 85005 8

**SAGE**  
PRODUCTS INC.  
3909 Three Oaks Road  
Cary, IL 60013  
www.sageproducts.com  
800-323-2220

Covered under U.S. Patent Nos. 7,066,916; 7,596,021; 7,427,574; 7,535,093; 7,717,889. Other Patents Pending.

NDC 053462-705-23

**SAGE**  
PRODUCTS INC.

**2% CHLORHEXIDINE GLUCONATE\* CLOTH**  
PATIENT PREOPERATIVE SKIN PREPARATION

\*equivalent to 500mg chlorhexidine gluconate per cloth

**NON-STERILE**

**Rinse-Free — Alcohol-Free**  
**For External Use Only — Single Use**

- Provides rapid bactericidal action against a broad spectrum of microorganisms
- Significantly reduces the number of microorganisms on intact skin
- Demonstrates continued antimicrobial activity for up to 6 hours after application

**2 disposable cloths**  
7.5in x 7.5in (19.1cm x 19.1cm)

**DO NOT MICROWAVE**

**Drug Facts**

Active ingredient	Purpose
Chlorhexidine gluconate 2% solution	Antiseptic

**Uses**

- helps reduce bacteria that can potentially cause skin infection
- for preparation of skin prior to surgery

**Warnings**

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**Stop use and ask a doctor if** irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition.

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- do not microwave
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**To open package**

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- grasp flap at top and pull down to tear flap away and expose foam
- hold outside of package to prevent foam and cloths to prep table, avoiding contact between cloths and outside of package to reduce risk of cloth contamination

**Or**

- using sterile scissors, cut off end seal of package

**DO NOT FLUSH CLOTHS IN TOILET**

**LATEX FREE**

8323C

3M Skin and Nasal Antiseptic

NDC 17518-060-04

Tear Here

NDC# 17518-060-04



**3M**

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



**Contents:**

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

**REF 192401**

3M Skin and Nasal Antiseptic  
NDC 17518-060-04



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

NDC 17518-060-04

34-8703-4145-9

0.14 fl oz (4 mL)

Read Drug Facts panel before use.

Made in U.S.A. by **3M Health Care**  
 St. Paul, MN 55144-1000 (U.S.A.) 1-800-228-3957

**SKIN ANTISEPSIS, ORAL CLEANSING, NASAL ANTISEPSIS**

chlorhexidine gluconate kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53462-008
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-008-28	1 in 1 KIT		

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKAGE	6
Part 2	1 BOTTLE	4 mL

**Part 1 of 2**

**CHLORHEXIDINE GLUCONATE**

chlorhexidine gluconate cloth

**Product Information**

<b>Item Code (Source)</b>	NDC:53462-705
<b>Route of Administration</b>	TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
chlorhexidine gluconate (UNII: MOR84MUD8E) (chlorhexidine - UNII:R4KO0DY52L)	chlorhexidine gluconate	500 mg

## Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
no noxynol-9 (UNII: 48Q180SH9T)	
polyorbate 20 (UNII: 7T1F30V5YH)	
dimethicone 350 (UNII: 2Y53S6ATLU)	
propylene glycol (UNII: 6DC9Q167V3)	
aloe vera leaf (UNII: ZY81Z83H0X)	
glycerin (UNII: PDC6A3C0OX)	
gluconolactone (UNII: WQ29KQ9POT)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-705-23	6 in 1 PACKAGE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021669	02/01/2006	

## Part 2 of 2

### 3M SKIN AND NASAL ANTISEPTIC

3m skin and nasal antiseptic solution

## Product Information

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)	POVIDONE-IODINE	5 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
LACTIC ACID (UNII: 33X04XA5AT)	
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)	
MALIC ACID (UNII: 817L1N4CKP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM IODIDE (UNII: F5WR8N145C)	
PEG-100 STEARATE (UNII: YD01N1999R)	

WATER (UNII: 059QF0KO0R)

XYLITOL (UNII: VCQ006KQ1E)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 POUCH		
1	NDC:17518-060-04	4 mL in 1 BOTTLE		

### Marketing Information

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

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021669	02/06/2012	

**Labeler** - Sage Products, Inc. (054326178)

### Establishment

Name	Address	ID/FEI	Business Operations
Sage Products, Inc.		054326178	MANUFACTURE(53462-008)

### Establishment

Name	Address	ID/FEI	Business Operations
3M ESPE Dental Products		078404534	MANUFACTURE(17518-060, 53462-705)

### Establishment

Name	Address	ID/FEI	Business Operations
3M Health Care LTD		218829455	MANUFACTURE(17518-060, 53462-705)

Revised: 10/2012

Sage Products, Inc.