

SKIN ANTISEPSIS, ORAL CLEANSING AND NASAL ANTISEPSIS SYSTEM- chlorhexidine gluconate
Sage Products, LLC

Nose to Toes: Skin Antisepsis, Oral Cleansing and Nasal Antisepsis System

Drug Facts

<i>Active Ingredient</i>	<i>Purpose</i>
Corinz™ Antiseptic Cleansing and Moisturizing Oral Rinse: Cetylpyridinium Chloride 0.05%	Antiseptic Rinse

Uses

- Aids in the removal of dental plaque, debris and secretions and helps reduce the chance of infection in minor oral irritation.

Warnings

Stop use and ask a doctor if:

- Sore mouth symptoms do not improve in 7 days.
- Swelling, rash or fever develops.
- Irritation, pain or redness persists or worsens.

Keep out of reach of children.

If more than used for antisepsis is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **Before opening**, turn package over, burst solution packet with thumbs.
- Peel lid to open.
- Brush teeth and oral cavity for approximately one minute.
- Instruct to expectorate.
- Use Applicator Swab for additional cleansing as needed.
- Discard after use.
- Use up to 4 times daily or as directed by a dentist or doctor.
- Children under 12 years of age: supervise use.
- Children under 3 years of age: consult a dentist or doctor.
- Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.
- Ensure foam is intact after use. If not, remove any particles from oral cavity.

Inactive Ingredients

Water, glycerin, xylitol, spearmint flavor, potassium sorbate, polysorbate 20, polysorbate 80, hydroxyethylcellulose, citric acid, sodium saccharin, menthol.

Drugs Facts

CHG 2%

Active Ingredient	<i>Purpose</i>
Chlorhexidine gluconate 2% solution	Antiseptic

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.

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

Keep out of reach of children

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

Directions

- 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 cm² 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 cm² 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

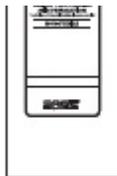
DO NOT FLUSH CLOTHS. Not made with Natural Rubber Latex.

Patents:

www.sageproducts.com/patents

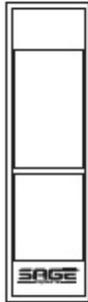
Nose to Toes: Skin Antisepsis, Oral Cleansing and Nasal Antisepsis System





- Three 2-packs of 2% Chlorhexidine Gluconate*
Cloth Patient Preoperative Skin Preparation
- * equivalent to 500mg chlorhexidine gluconate per cloth

Use as directed.



Oral Cleansing

Contents:

- One 7ml Burst Pouch of Corinz™ Antiseptic Cleansing and Moisturizing Oral Rinse
- 1 Ultra-Soft Toothbrush
- 1 Applicator Swab treated with Sodium Bicarbonate

Use as directed.

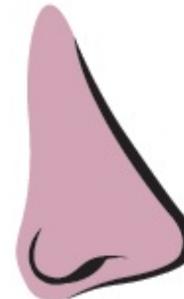


Nasal Antisepsis

Contents:

- 1 Bottle of 3M™ Skin and Nasal Antiseptic (Povidone-Iodine Solution 5% w/w (0.5% available iodine) USP) Patient Preoperative Skin Preparation 0.14 fl oz (4 mL)
- 4 sterile swabs.

Use as directed.



For detailed listing of ingredients, see the enclosed individual packages.

Not made with natural rubber latex
Patents: www.sageproducts.com/patents



Made in U.S.A.

Reorder # 9010

SAGE[®]
PRODUCTS

Sage Products LLC
3909 Three Oaks Road • Cary, Illinois 60013
www.sageproducts.com
800-323-2220

▶ TEAR HERE ▶

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 cm² 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 cm² 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



SAGE PRODUCTS LLC
3909 Three Oaks Road
Cary, Illinois 60013
www.sageproducts.com
800-323-2220

Patents:
www.sageproducts.com/patents
R5335D

NDC 053462-705-23



2% CHLORHEXIDINE GLUCONATE* CLOTH

PATIENT PREOPERATIVE SKIN PREPARATION

NON-STERILE

*equivalent to 500mg chlorhexidine gluconate per cloth

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

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.

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

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

Directions

- 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



DO NOT FLUSH CLOTHS
LATEX FREE



Antiseptic Cleansing & Moisturizing Oral Rinse

Active Ingredient:
Cetylpyridinium
chloride 0.05%

Squeeze Here



To Release Fluid

**BURST PACKET
BEFORE OPENING
OUTER PACKAGE**

Do not remove
from package

0.25 fl. oz./7 mL

R5439



Antiseptic Cleansing & Moisturizing Oral Rinse

Active Ingredient:
Cetylpyridinium
chloride 0.05%

Squeeze Here



To Release Fluid

**BURST PACKET
BEFORE OPENING
OUTER PACKAGE**

Do not remove
from package

0.25 fl. oz./7 mL



LOT

Ultra-Soft Toothbrush with Applicator Swab and Corinz™ Antiseptic Cleansing & Moisturizing Oral Rinse

CONTENTS: 1 Ultra-Soft Toothbrush, 1 Applicator Swab
with sodium bicarbonate, 0.25 fl. oz./7ml Corinz
Antiseptic Cleansing and Moisturizing Oral Rinse

Drug Facts

Active ingredient

CORINZ ANTISEPTIC CLEANSING AND

Purpose

MOISTURIZING ORAL RINSE:

Cetylpyridinium chloride 0.05%.....Antiseptic Rinse

Uses

- Aids in the removal of dental plaque, debris and secretions and helps reduce the chance of infection in minor oral irritation.

Warnings

Stop use and ask a doctor if:

- Sore mouth symptoms do not improve in 7 days.
- Swelling, rash or fever develops.
- Irritation, pain or redness persists or worsens.

Keep out of reach of children.

If more than used for antisepsis is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **Before opening**, turn package over, burst solution packet with thumbs.
 - Peel lid to open.
 - Brush teeth and oral cavity for approximately one minute.
 - Instruct to expectorate.
 - Use Applicator Swab for additional cleansing as needed.
 - Discard after use.
-
- Use up to 4 times daily or as directed by a dentist or doctor.
 - Children under 12 years of age: supervise use.
 - Children under 3 years of age: consult a dentist or doctor.
 - Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.
 - Ensure foam is intact after use. If not, remove any particles from oral cavity.

Inactive ingredients

Water, glycerin, xylitol, spearmint flavor, potassium sorbate, polysorbate 20, polysorbate 80, hydroxyethylcellulose, citric acid, sodium saccharin, menthol.

Questions? Call toll-free 800-323-2220.

Sodium Bicarbonate ingredients*: Water (aqua), sodium bicarbonate, cellulose gum, sodium lauryl sulfate, flavor (aroma), sodium saccharin, sodium benzoate.

* Manufactured for Sage Products LLC

**NOT MADE WITH NATURAL RUBBER LATEX
FOR SINGLE USE ONLY • MADE IN U.S.A.**

SAGE[®]
PRODUCTS

Sage Products LLC
3909 Three Oaks Road • Cary, Illinois 60013
www.sageproducts.com • 800-323-2220

Patents: www.sageproducts.com/patents

R5496

3M Skin and Nasal Antiseptic

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

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
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: 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: 3M.com/Patents
Made in U.S.A. by 3M Health Care, 2510 Conway Ave., St. Paul, MN 55144
© 2012, 3M. 3M is a trademark of 3M. 34-8710-5699-9

Tear Here

NDC# 17518-060-04



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

192401^{REF}

SKIN ANTISEPSIS, ORAL CLEANSING AND NASAL ANTISEPSIS SYSTEM

chlorhexidine gluconate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53462-110
--------------	----------------	--------------------	---------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-110-29	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	12/28/2016	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKAGE	6
Part 2	1 PACKET	7 mL
Part 3		1
Part 4	1 BOTTLE	4 mL

Part 1 of 4

CHLORHEXIDINE GLUCONATE

chlorhexidine gluconate cloth

Product Information

Item Code (Source)	NDC:53462-705
--------------------	---------------

Route of Administration	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)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
POLYSORBATE 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		6 in 1 KIT		
1	NDC:53462-705-23	6 in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information

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

Part 2 of 4

CORINZ

cetylpyridinium chloride rinse

Product Information

Item Code (Source)	NDC:53462-375
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7J10JV3)	CETYLPYRIDINIUM CHLORIDE	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HYDROXYETHYL CELLULOSE (4000 MPAS AT 1%) (UNII: ZYD53NBL45)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NDC:53462-375-60	1 in 1 KIT		
1		7 mL in 1 PACKET; 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	part356	01/20/2016	

Part 3 of 4

SODIUM BICARBONATE

other oral hygiene products

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
INGR	CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
INGR	SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Part 4 of 4

3M SKIN AND NASAL ANTISEPTIC

povidone-iodine 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)	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)	
STEARETH-100 (UNII: 4OH5W9UM87)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 KIT		
1	NDC:17518-060-04	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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021669	12/28/2016	

Labeler - Sage Products, LLC (054326178)

Registrant - Sage Products, LLC (054326178)

Establishment

Name	Address	ID/FEI	Business Operations
Sage Products, LLC		054326178	manufacture(53462-110, 53462-705, 53462-375)

Establishment

Name	Address	ID/FEI	Business Operations
3M Health Care LTD		218829455	manufacture(17518-060)