

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

Use

Helps reduce 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

Allergy alert:

This product may cause a severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- on patients allergic to chlorhexidine gluconate or any other ingredient 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



and oral cleansing



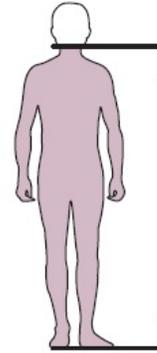
Skin Antisepsis

Contents:

- 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.



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 # **9009**

SAGE[®]
PRODUCTS

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



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
MOISTURIZING ORAL RINSE:

Cetylpyridinium chloride 0.05%.....Antiseptic Rinse

Purpose

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.**

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PRODUCTS

Sage Products LLC
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Patents: www.sageproducts.com/patents

R5496

▶ TEAR HERE ▶

Drug Facts (continued)

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, dimethylsiloxane, fragrance, glucono-delta-lactone, glycerin, Isopropyl alcohol, propylene glycol, USP purified water
cloth: polyester

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

DO NOT FLUSH CLOTHS
Not made with natural rubber latex

Reorder #9707



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Sage Products LLC
3909 Three Dates Road
Cary, Illinois 60013
sageproducts.com
800 323 2220
Patients: sageproducts.com/patients
ne0362

NDC 53462-705-23

SAGE PRODUCTS

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
7.5 in x 7.5 in (19.1 cm x 19.1 cm)

DO NOT MICROWAVE

Drug Facts

Active ingredient	Purpose
Chlorhexidine gluconate	Antiseptic
2% solution	

Uses

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

Warnings
For external use only

Allergy alert:
This product may cause a severe allergic reaction. Symptoms may include:

- wheezing / difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

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- for lacerations 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
- grip 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

SKIN ANTISEPSIS, ORAL CLEANSING AND NASAL ANTISEPSIS SYSTEM
chlorhexidine gluconate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53462-009
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:53462-009-24	1 in 1 KIT; Type 0: Not a Combination Product	12/28/2016
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Quantity of Parts

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

Part 1 of 3

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
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NDA	NDA021669	02/01/2006	
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Part 2 of 3

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: 059QF0K00R)	
INGR	SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Marketing Information

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

Part 3 of 3

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
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYL PYRIDINIUM - UNII: CUB7JI0JV3)	CETYL PYRIDINIUM CHLORIDE	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)	
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	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	01/20/2015	

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(53462-009, 53462-705, 53462-375)