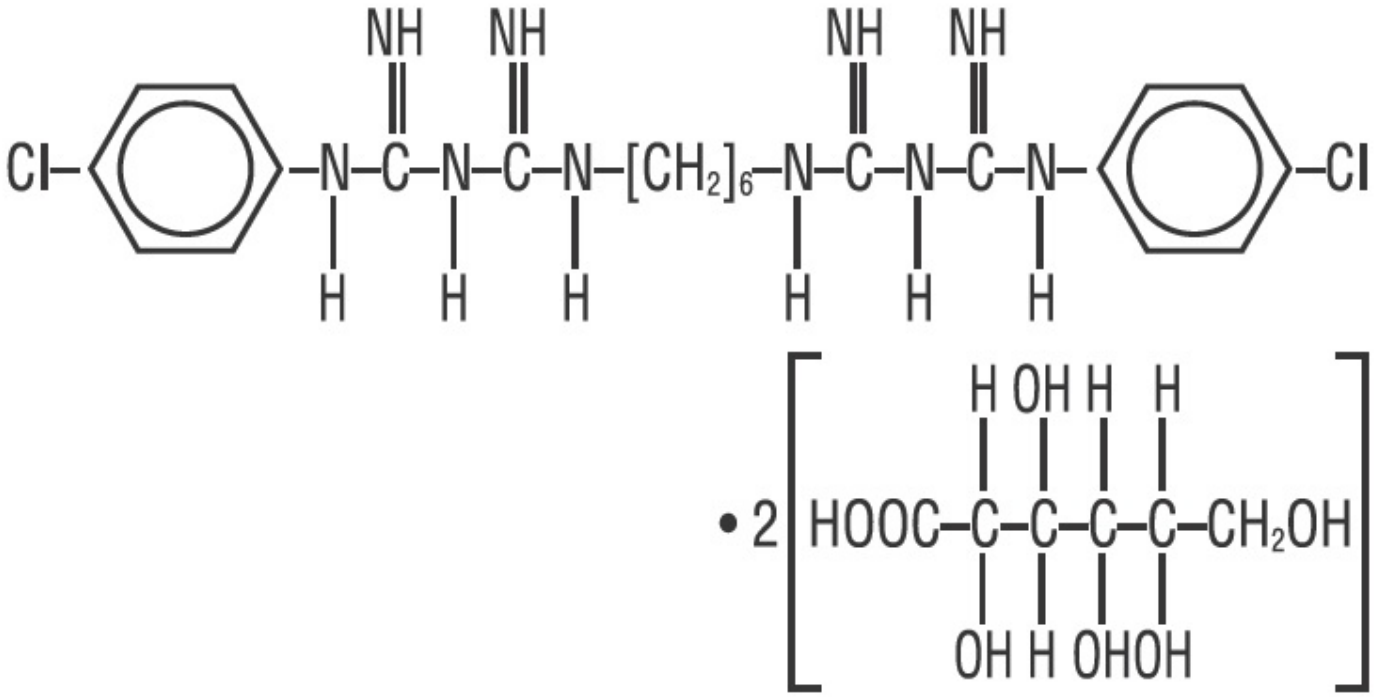
SKIN ANTISEPSIS, ORAL CLEANSING, NASAL ANTISEPSIS- chlorhexidine gluconate
Sage Products LLC

Skin Antisepsis, oral cleansing, nasal antisepsis

CHLORHEXIDINE GLUCONTATE 0.12% ORAL RINSE

DESCRIPTION

Chlorhexidine Gluconate is an oral rinse containing 0.12% chlorhexidine gluconate (1,11-hexamethylene bis[5-(p-chlorophenyl) biguanide] di-D-gluconate) in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin, and FD&C Blue No. 1. Chlorhexidine Gluconate is a near-neutral solution (pH range 5-7). Chlorhexidine Gluconate is a salt of chlorhexidine and gluconic acid. Its chemical structure is:



CLINICAL PHARMACOLOGY

Chlorhexidine Gluconate Oral Rinse provides antimicrobial activity during oral rinsing. The clinical significance of Chlorhexidine Gluconate Oral Rinse's antimicrobial activities is not clear. Microbiological sampling of plaque has shown a general reduction of counts of certain assayed bacteria, both aerobic and anaerobic, ranging from 54-97% through six months use.

Use of Chlorhexidine Gluconate Oral Rinse in a six month clinical study did not result in any significant changes in bacterial resistance, overgrowth of potentially opportunistic organisms or other adverse changes in the oral microbial ecosystem. Three months after Chlorhexidine Gluconate Oral Rinse was discontinued, the number of bacteria in plaque had returned to baseline levels and resistance of plaque bacteria to chlorhexidine gluconate was equal to that at baseline.

PHARMACOKINETICS

Pharmacokinetic studies with Chlorhexidine Gluconate Oral Rinse indicate approximately 30% of the active ingredient, chlorhexidine gluconate, is retained in the oral cavity following rinsing. This retained drug is slowly released in the oral fluids. Studies conducted on human subjects and animals demonstrate chlorhexidine gluconate is poorly absorbed from the gastrointestinal tract. The mean plasma level of

chlorhexidine gluconate reached a peak of 0.206 mcg/g in humans 30 minutes after they ingested a 300 mg dose of the drug. Detectable levels of chlorhexidine gluconate were not present in the plasma of these subjects 12 hours after the compound was administered. Excretion of chlorhexidine gluconate occurred primarily through the feces (~90%). Less than 1% of the chlorhexidine gluconate ingested by these subjects was excreted in the urine.

INDICATIONS AND USAGE

Chlorhexidine Gluconate Oral Rinse is indicated for use between dental visits as part of a professional program for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing. Chlorhexidine Gluconate Oral Rinse has not been tested among patients with acute necrotizing ulcerative gingivitis (ANUG). For patients having coexisting gingivitis and periodontitis, see PRECAUTIONS.

CONTRAINDICATIONS

Chlorhexidine Gluconate Oral Rinse should not be used by persons who are known to be hypersensitive to chlorhexidine gluconate or other formula ingredients.

WARNINGS

The effect of Chlorhexidine Gluconate Oral Rinse on periodontitis has not been determined. An increase in supragingival calculus was noted in clinical testing in Chlorhexidine Gluconate Oral Rinse users compared with control users. It is not known if Chlorhexidine Gluconate Oral Rinse use results in an increase in subgingival calculus. Calculus deposits should be removed by a dental prophylaxis at intervals not greater than six months. Anaphylaxis, as well as serious allergic reactions, have been reported during postmarketing use with dental products containing chlorhexidine, see CONTRAINDICATIONS.

PRECAUTIONS

GENERAL

1. For patients having coexisting gingivitis and periodontitis, the presence or absence of gingival inflammation following treatment with Chlorhexidine Gluconate Oral Rinse should not be used as a major indicator of underlying periodontitis.
2. Chlorhexidine Gluconate Oral Rinse can cause staining of oral surfaces, such as tooth surfaces, restorations, and the dorsum of the tongue. Not all patients will experience a visually significant increase in toothstaining. In clinical testing, 56% of Chlorhexidine Gluconate Oral Rinse users exhibited a measurable increase in facial anterior stain, compared to 35% of control users after six months; 15% of Chlorhexidine Gluconate Oral Rinse users developed what was judged to be heavy stain, compared to 1% of control users after six months. Stain will be more pronounced in patients who have heavier accumulations of unremoved plaque. Stain resulting from use of Chlorhexidine Gluconate Oral Rinse does not adversely affect health of the gingivae or other oral tissues. Stain can be removed from most tooth surfaces by conventional professional prophylactic techniques. Additional time may be required to complete the prophylaxis. Discretion should be used when prescribing to patients with anterior facial restorations with rough surfaces or margins. If natural stain cannot be removed from these surfaces by a dental prophylaxis, patients should be excluded from Chlorhexidine Gluconate Oral Rinse treatment if permanent discoloration is unacceptable. Stain in these areas may be difficult to remove by dental prophylaxis and on rare occasions may necessitate replacement of these restorations.
3. Some patients may experience an alteration in taste perception while undergoing treatment with Chlorhexidine Gluconate Oral Rinse. Rare instances of permanent taste alteration following

Chlorhexidine Gluconate Oral Rinse use have been reported via post-marketing product surveillance.

ADVERSE REACTIONS

The most common side effects associated with chlorhexidine gluconate oral rinses are: 1) an increase in staining of teeth and other oral surfaces; 2) an increase in calculus formation; and 3) an alteration in taste perception; see WARNINGS and PRECAUTIONS. Oral irritation and local allergy-type symptoms have been spontaneously reported as side effects associated with use of chlorhexidine gluconate rinse. The following oral mucosal side effects were reported during placebo-controlled adult clinical trials: aphthous ulcer, grossly obvious gingivitis, trauma, ulceration, erythema, desquamation, coated tongue, keratinization, geographic tongue, mucocele, and short frenum. Each occurred at a frequency of less than 1%. Among post marketing reports, the most frequently reported oral mucosal symptoms associated with Chlorhexidine Gluconate Oral Rinse are stomatitis, gingivitis, glossitis, ulcer, dry mouth, hypesthesia, glossal edema, and paresthesia. Minor irritation and superficial desquamation of the oral mucosa have been noted in patients using Chlorhexidine Gluconate Oral Rinse. There have been cases of parotid gland swelling and inflammation of the salivary glands (sialadenitis) reported in patients using Chlorhexidine Gluconate Oral Rinse.

OVERDOSAGE

Ingestion of 1 or 2 ounces of Chlorhexidine Gluconate Oral Rinse by a small child (~10 kg body weight) might result in gastric distress, including nausea, or signs of alcohol intoxication. Medical attention should be sought if more than 4 ounces of Chlorhexidine Gluconate Oral Rinse is ingested by a small child or if signs of alcohol intoxication develop.

DOSAGE AND ADMINISTRATION

Chlorhexidine Gluconate Oral Rinse therapy should be initiated directly following a dental prophylaxis. Patients using Chlorhexidine Gluconate Oral Rinse should be reevaluated and given a thorough prophylaxis at intervals no longer than six months. Recommended use is twice daily oral rinsing for 30 seconds, morning and evening after toothbrushing. Usual dosage is 15 mL of undiluted Chlorhexidine Gluconate Oral Rinse. Patients should be instructed to not rinse with water, or other mouthwashes, brush teeth, or eat immediately after using Chlorhexidine Gluconate Oral Rinse. Chlorhexidine Gluconate Oral Rinse is not intended for ingestion and should be expectorated after rinsing.

HOW SUPPLIED

Chlorhexidine Gluconate Oral Rinse is supplied as a blue liquid in single dose 0.5 fluid ounce (15mL) amber plastic bottles with child-resistant dispensing closures. **STORE at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP controlled room temperature].**

Rx only. KEEP OUT OF REACH OF CHILDREN.

WHAT TO EXPECT WHEN USING CHLORHEXIDINE GLUCONATE ORAL RINSE

Your dentist has prescribed Chlorhexidine Gluconate Oral Rinse to treat your gingivitis, to help reduce the redness, and swelling of your gums, and also to help you control any gum bleeding. Use Chlorhexidine Gluconate Oral Rinse regularly, as directed by your dentist, in addition to daily brushing. Spit out after use. Chlorhexidine Gluconate Oral Rinse should not be swallowed.

If you develop allergic symptoms such as skin rash, itch, generalized swelling, breathing difficulties, light headedness, rapid heart rate, upset stomach or diarrhea, seek medical attention immediately. Chlorhexidine Gluconate Oral Rinse should not be used by persons who have a sensitivity to it or its

components.

Chlorhexidine Gluconate Oral Rinse may cause some tooth discoloration, or increase in tartar (calculus) formation, particularly in areas where stain and tartar usually form. It is important to see your dentist for removal of any stain or tartar at least every six months or more frequently if your dentist advises.

Both stain and tartar can be removed by your dentist or hygienist. Chlorhexidine Gluconate Oral Rinse may cause permanent discoloration of some front-tooth fillings.
To minimize discoloration, you should brush and floss daily, emphasizing areas which begin to discolor.
Chlorhexidine Gluconate Oral Rinse may taste bitter to some patients and can affect how foods and beverages taste. This will become less noticeable in most cases with continued use of Chlorhexidine Gluconate Oral Rinse.
To avoid taste interference, rinse with Chlorhexidine Gluconate Oral Rinse after meals. Do not rinse with water or other mouthwashes immediately after rinsing with Chlorhexidine Gluconate Oral Rinse.
If you have any questions or comments about Chlorhexidine Gluconate Oral Rinse, contact your dentist or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

INGREDIENTS: 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin, and FD&C Blue No. 1.

STORE at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP controlled room temperature].

Manufactured for:
Sage Products LLC
Cary, IL 60013

1-800-323-2220

Revised: October, 2018

SAGE15ORBTLLBLB

2% CHLORHEXIDINE GLUCONATE CLOTH

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

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 cleanse

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.

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)

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

cloth: polyester

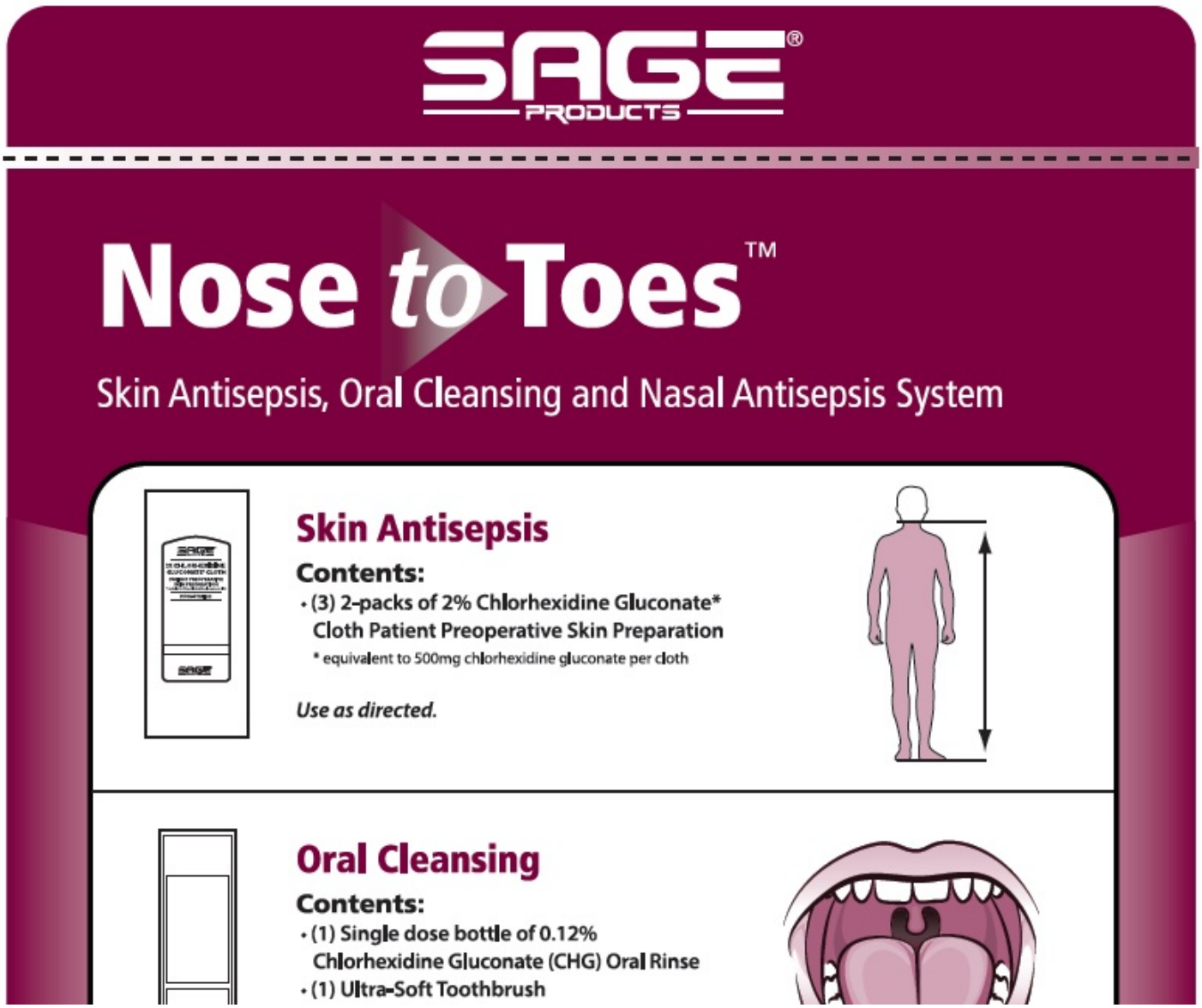
QUESTIONS OR COMMENTS?

call toll-free 800-323-2220

(Monday to Friday 8 AM - 5 PM CST)

www.sageproducts.com

SKIN ANTISEPSIS, ORAL CLEANSING, NASAL ANTISEPSIS



- (1) Untreated Swab

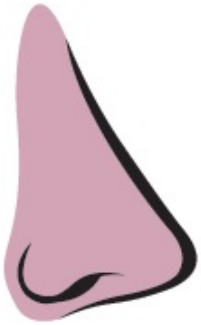
Use as directed.

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

6 18029 85018 8

Made in U.S.A.

R4662B

Reorder #9011

SAGE® PRODUCTS

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

▼ 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 cm^2 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^2 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, Isopalt®, 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

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SAGE PRODUCTS

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

Patents:
www.sageproducts.com/patents

RS335F

NDC 053462-705-23

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
7.5in 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

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

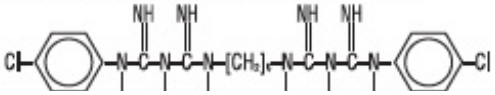
NOT MADE WITH NATURAL RUBBER LATEX

SAGE® PRODUCTS

Chlorhexidine Gluconate 0.12% Oral Rinse

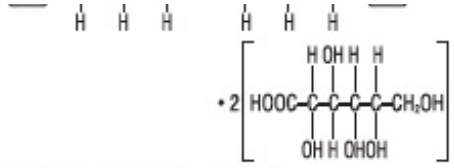
NDC 53462-003-15

DESCRIPTION: Chlorhexidine Gluconate is an oral rinse containing 0.12% chlorhexidine gluconate (1,1[1]-hexamethylene bis[5-(p-chlorophenyl) biguanide] di-D-gluconate) in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin, and FD&C Blue No. 1. Chlorhexidine Gluconate is a near-neutral solution (pH range 5-7). Chlorhexidine Gluconate is a salt of chlorhexidine and gluconic acid. Its chemical structure is:



chlorhexidine gluconate. The highest doses of chlorhexidine used in a mouse dominant-lethal assay and a hamster cytogenetics test were 1000 mg/kg/day and 250 mg/kg/day, respectively. No evidence of impaired fertility was observed in rats at doses up to 100 mg/kg/day.

ADVERSE REACTIONS: The most common side effects associated with chlorhexidine gluconate oral rinses are: 1) an increase in staining of teeth and other oral surfaces; 2) an increase in calculus formation; and 3) an alteration in taste perception; see WARNINGS and PRECAUTIONS. Oral irritation and local allergy-type symptoms have been spontaneously reported as side effects associated with use of chlorhexidine gluconate rinse. The following oral mucosal side effects were reported during placebo-controlled adult



CLINICAL PHARMACOLOGY: Chlorhexidine Gluconate Oral Rinse provides antimicrobial activity during oral rinsing. The clinical significance of Chlorhexidine Gluconate Oral Rinse's antimicrobial activities is not clear. Microbiological sampling of plaque has shown a general reduction of counts of certain assayed bacteria, both aerobic and anaerobic, ranging from 54-97% through six months use.

Use of Chlorhexidine Gluconate Oral Rinse in a six month clinical study did not result in any significant changes in bacterial resistance, overgrowth of potentially opportunistic organisms or other adverse changes in the oral microbial ecosystem. Three months after Chlorhexidine Gluconate Oral Rinse was discontinued, the number of bacteria in plaque had returned to baseline levels and resistance of plaque bacteria to chlorhexidine gluconate was equal to that at baseline.

PHARMACOKINETICS: Pharmacokinetic studies with Chlorhexidine Gluconate Oral Rinse indicate approximately 30% of the active ingredient, chlorhexidine gluconate, is retained in the oral cavity following rinsing. This retained drug is slowly released in the oral fluids. Studies conducted on human subjects and animals demonstrate chlorhexidine gluconate is poorly absorbed from the gastrointestinal tract. The mean plasma level of chlorhexidine gluconate reached a peak of 0.206 mcg/g in humans 30 minutes after they ingested a 300 mg dose of the drug. Detectable levels of chlorhexidine gluconate were not present in the plasma of these subjects 12 hours after the compound was administered. Excretion of chlorhexidine gluconate occurred primarily through the feces (~90%). Less than 1% of the chlorhexidine gluconate ingested by these subjects was excreted in the urine.

INDICATION AND USAGE: Chlorhexidine Gluconate Oral Rinse is indicated for use between dental visits as part of a professional program for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing. Chlorhexidine Gluconate Oral Rinse has not been tested among patients with acute necrotizing ulcerative gingivitis (ANUG). For patients having coexisting gingivitis and periodontitis, see PRECAUTIONS.

CONTRAINDICATIONS: Chlorhexidine Gluconate Oral Rinse should not be used by persons who are known to be hypersensitive to chlorhexidine gluconate or other formula ingredients.

WARNINGS: The effect of Chlorhexidine Gluconate Oral Rinse on periodontitis has not been determined. An increase in supragingival calculus was noted in clinical testing in Chlorhexidine Gluconate Oral Rinse users compared with control users. It is not known if Chlorhexidine Gluconate Oral Rinse use results in an increase in subgingival calculus. Calculus deposits should be removed by a dental prophylaxis at intervals not greater than six months. Anaphylaxis, as well as serious allergic

2.4688"

clinical trials: aphthous ulcer, grossly obvious gingivitis, trauma, ulceration, erythema, desquamation, coated tongue, keratinization, geographic tongue, mucocele, and short frenum. Each occurred at a frequency of less than 1%. Among post marketing reports, the most frequently reported oral mucosal symptoms associated with Chlorhexidine Gluconate Oral Rinse are stomatitis, gingivitis, glossitis, ulcer, dry mouth, hypesthesia, glossal edema, and paresthesia. Minor irritation and superficial desquamation of the oral mucosa have been noted in patients using Chlorhexidine Gluconate Oral Rinse. There have been cases of parotid gland swelling and inflammation of the salivary glands (sialadenitis) reported in patients using Chlorhexidine Gluconate Oral Rinse.

OVERDOSAGE: Ingestion of 1 or 2 ounces of Chlorhexidine Gluconate Oral Rinse by a small child (~10 kg body weight) might result in gastric distress, including nausea, or signs of alcohol intoxication. Medical attention should be sought if more than 4 ounces of Chlorhexidine Gluconate Oral Rinse is ingested by a small child or if signs of alcohol intoxication develop.

DOSAGE AND ADMINISTRATION: Chlorhexidine Gluconate Oral Rinse therapy should be initiated directly following a dental prophylaxis. Patients using Chlorhexidine Gluconate Oral Rinse should be reevaluated and given a thorough prophylaxis at intervals no longer than six months. Recommended use is twice daily oral rinsing for 30 seconds, morning and evening after toothbrushing. Usual dosage is 15 mL of undiluted Chlorhexidine Gluconate Oral Rinse. Patients should be instructed to not rinse with water, or other mouthwashes, brush teeth, or eat immediately after using Chlorhexidine Gluconate Oral Rinse. Chlorhexidine Gluconate Oral Rinse is not intended for ingestion and should be expectorated after rinsing.

HOW SUPPLIED: Chlorhexidine Gluconate Oral Rinse is supplied as a blue liquid in single dose 0.5 fluid ounce (15mL) amber plastic bottles with child-resistant dispensing closures. ***STORE* at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP controlled Room Temperature].**

Rx only. KEEP OUT OF REACH OF CHILDREN.

WHAT TO EXPECT WHEN USING CHLORHEXIDINE GLUCONATE ORAL RINSE

Your dentist has prescribed Chlorhexidine Gluconate Oral Rinse to treat your gingivitis, to help reduce the redness, and swelling of your gums, and also to help you control any gum bleeding. Use Chlorhexidine Gluconate Oral Rinse regularly, as directed by your dentist, in addition to daily brushing. Spit out after use. Chlorhexidine Gluconate Oral Rinse should not be swallowed.

If you develop allergic symptoms such as skin rash, itch, generalized swelling, breathing difficulties, light headedness, rapid heart rate, upset stomach or diarrhea, seek medical attention immediately. Chlorhexidine Gluconate Oral Rinse should not be used by persons who have a sensitivity to it or its components.

Chlorhexidine Gluconate Oral Rinse may cause some tooth discoloration, or increase in tartar (calculus) formation, particularly in areas where stain and tartar usually form. It is important to

reactions, have been reported during postmarketing use with dental products containing chlorhexidine, see CONTRAINDICATIONS.

PRECAUTIONS:
GENERAL:

1. For patients having coexisting gingivitis and periodontitis, the presence or absence of gingival inflammation following treatment with Chlorhexidine Gluconate Oral Rinse should not be used as a major indicator of underlying periodontitis.
2. Chlorhexidine Gluconate Oral Rinse can cause staining of oral surfaces, such as tooth surfaces, restorations, and the dorsum of the tongue. Not all patients will experience a visually significant increase in toothstaining. In clinical testing, 56% of Chlorhexidine Gluconate Oral Rinse users exhibited a measurable increase in facial anterior stain, compared to 35% of control users after six months; 15% of Chlorhexidine Gluconate Oral Rinse users developed what was judged to be heavy stain, compared to 1% of control users after six months. Stain will be more pronounced in patients who have heavier accumulations of unremoved plaque. Stain resulting from use of Chlorhexidine Gluconate Oral Rinse does not adversely affect health of the gingivae or other oral tissues. Stain can be removed from most tooth surfaces by conventional professional prophylactic techniques. Additional time may be required to complete the prophylaxis. Discretion should be used when prescribing to patients with anterior facial restorations with rough surfaces or margins. If natural stain cannot be removed from these surfaces by a dental prophylaxis, patients should be excluded from Chlorhexidine Gluconate Oral Rinse treatment if permanent discoloration is unacceptable. Stain in these areas may be difficult to remove by dental prophylaxis and on rare occasions may necessitate replacement of these restorations.
3. Some patients may experience an alteration in taste perception while undergoing treatment with Chlorhexidine Gluconate Oral Rinse. Rare instances of permanent taste alteration following Chlorhexidine Gluconate Oral Rinse use have been reported via post-marketing product surveillance.

PREGNANCY: TERATOGENIC EFFECTS
Pregnancy Category B. Reproduction Studies have been performed in rats and rabbits at chlorhexidine gluconate doses up to 300 mg/kg/day and 40 mg/kg/day respectively, and have not revealed evidence of harm to fetus. However, adequate and well-controlled studies in pregnant women have not been done. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

NURSING MOTHERS: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Chlorhexidine Gluconate Oral Rinse is administered to nursing women. In parturition and lactation studies with rats, no evidence of impaired parturition or of toxic effects to suckling pups was observed when chlorhexidine gluconate was administered to dams at doses that were over 100 times greater than that which would result from a

stain and tartar usually form. It is important to see your dentist for removal of any stain or tartar at least every six months or more frequently if your dentist advises.

- Both stain and tartar can be removed by your dentist or hygienist. Chlorhexidine Gluconate Oral Rinse may cause permanent discoloration of some front-tooth fillings.
- To minimize discoloration, you should brush and floss daily, emphasizing areas which begin to discolor.
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- To avoid taste interference, rinse with Chlorhexidine Gluconate Oral Rinse *after* meals. Do not rinse with water or other mouthwashes immediately after rinsing with Chlorhexidine Gluconate Oral Rinse.

If you have any questions or comments about Chlorhexidine Gluconate Oral Rinse, contact your dentist or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

INGREDIENTS: 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin, and FD&C Blue No. 1.

STORE at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP controlled Room Temperature].

Manufactured for:
Sage Products LLC
Cary, IL 60013

1-800-323-2220

Revised: November, 2015

SAGE15ORBTLLBLC

SAGE® PRODUCTS

NDC 53462-003-15

CHLORHEXIDINE GLUCONATE 0.12% ORAL RINSE

DIRECTIONS FOR USE: Swish in mouth undiluted for 30 seconds, then **spit out**. Use after breakfast and before bedtime, or use as prescribed. NOTE: To minimize medicinal taste, rinse with water immediately after use. **To open, press down while turning** to unseal, turn cap past "clicks" until tightly locked.

KEEP OUT OF REACH OF CHILDREN

16 fl oz (15 mL)

person's ingesting 30 mL of Chlorhexidine Gluconate Oral Rinse per day.

PEDIATRIC USE: Clinical effectiveness and safety of Chlorhexidine Gluconate Oral Rinse have not been established in children under the age of 18.

CARCINOGENESIS, MUTAGENESIS, AND IMPAIRMENT OF FERTILITY: In a drinking water study in rats, carcinogenic effects were not observed at doses up to 38 mg/kg/day. Mutagenic effects were not observed in two mammalian *in vivo* mutagenesis studies with

SKIN ANTISEPSIS, ORAL CLEANSING, NASAL ANTISEPSIS

chlorhexidine gluconate kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53462-007

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53462-007-27	1 in 1 KIT	02/06/2012	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 PACKAGE	6
Part 2	1 BOTTLE	4 mL
Part 3	1 BOTTLE	15 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	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 3

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)	
MALIC ACID (UNII: 817L1N4CKP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM IODIDE (UNII: F5WR8N145C)	
STEARETH-100 (UNII: 4OH5W9UM87)	
WATER (UNII: 059QF0KO0R)	

XYLITOL (UNII: VCQ006KQ1E)	
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 KIT		
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	

Part 3 of 3

CHLORHEXIDINE GLUCONATE 0.12% ORAL RINSE

chlorhexidine gluconate liquid

Product Information

Item Code (Source)	NDC:53462-003
Route of Administration	BUCCAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	1.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-40 SORBITAN DIISOSTEARATE (UNII: JL4CCU7I1G)	
ALCOHOL (UNII: 3K9958V90M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-003-15	15 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
ANDA	ANDA077789	01/20/2014	

Marketing Information

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

Labeler - Sage Products LLC (054326178)

Registrant - Sage Products LLC (054326178)

Establishment

Name	Address	ID/FEI	Business Operations
Sage Products LLC		054326178	manufacture(53462-007, 53462-705)

Revised: 5/2019 Sage Products LLC