QCARE RX ORAL CLEANSING AND SUCTIONING SYSTEM, Q4- chlorhexidine gluconate and hydrogen peroxide
Sage Products LLC

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.

QCare Rx Oral Cleansing and Suctioning System, Q4

Drug Facts

Suction Swab with Perox-A-Mint Solution

Active Ingredient:	***Purpose***
PEROX-A-MINT:	
Hydrogen Peroxide 1.5%	Oral Debriding Agent

Suction Toothbrush CHG compatible*

*Compatible for use with 0.12% Chlorhexidine Gluconate (CHG) oral rinse, tested for use up to five minutes.
NOTE: The following Uses and Directions refer to the Suction Toothbrush and Swab. For Warnings, Uses and Directions specific to the CHG rinse including use in children under 18 years of age, refer to that product's package insert and labeling.

USES

Suction Swab with Perox-A-Mint Solution
- Aids in the removal of secretions and debris.

Suction Toothbrush CHG compatible*
- Aids in the removal of dental plaque, debris and secretions.

Oropharyngeal Suction Catheter Non-sterile
- Aids in the removal of secretions from the oropharyngeal cavity only.

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 debriding is accidentally swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS

Suction Swab with Perox-A-Mint Solution
- **Before opening,** turn package over, burst solution packet with thumbs.
- Peel lid to open.

- Remove Mouth Moisturizer and Applicator Swab.
- Attach Suction Swab to Suction Handle.
- Clean teeth and oral cavity for approximately one minute.
- To suction, slide switch to ON. When finished, return switch to OFF.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Suction Swab. Reattach Covered Yankauer to Suction Handle.
- Place Mouth Moisturizer on Applicator Swab.
- Apply as needed to lips and inside mouth.
- 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.

Suction Toothbrush CHG compatible*

- Peel lid to open.
- Remove Suction Toothbrush and attach to Suction Handle.
- When using with a cleansing solution, refer to the product packaging for indications, instructions and warnings.
- To suction, place thumb over port.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Suction Toothbrush. Reattach Covered Yankauer to Suction Handle.
- Use Swab for additional cleansing as needed.
- Use two 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.

Oropharyngeal Suction Catheter Non-sterile

- Peel lid to open.
- Attach Suction Catheter to Suction Handle.
- Suction secretions from the oropharyngeal cavity.
- To suction, slide switch to ON. When finished, return switch to OFF.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Suction Catheter. Reattach Covered Yankauer to Suction Handle.
- Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.

Oropharyngeal Suction Catheter Non-sterile

Caution

- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or licensed practitioner.

Inactive Ingredients

Suction Swab with Perox-A-Mint Solution
Water, menthol flavor, polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI 42090), Yellow 6 (CI 15985)

Questions?

Call toll-free 800–323–2220

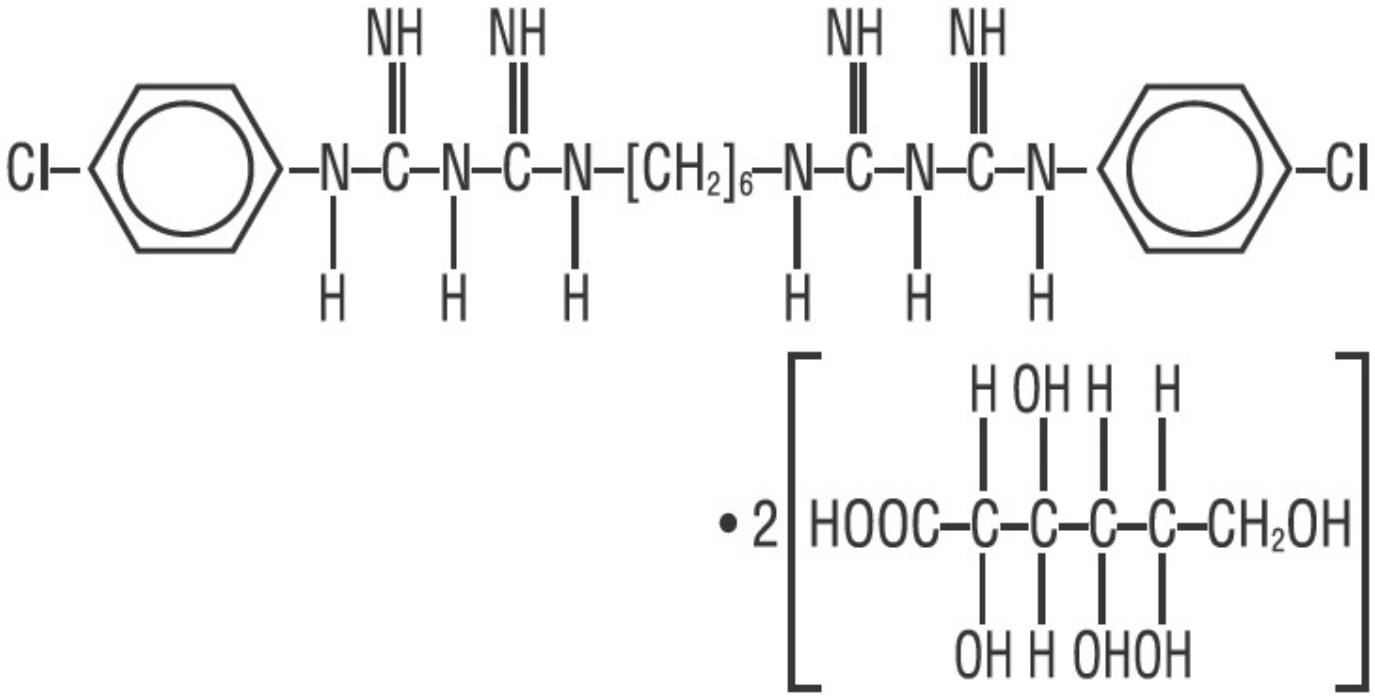
Manufactured for Sage Products LLC Cary, IL

CHLORHEXIDINE GLUCONATE ORAL RINSE, 0.12%

Rx Only

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:



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 µg/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.

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 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, 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 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 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 1.0%. 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].**

Keep out of reach of children

Manufactured for:
Sage Products LLC
Cary, IL 60013

1-800-323-2220

Revised: September, 2013

SAGE15ORBTLLBLB

Q·Care® Rx Oral Cleansing and Suctioning System

Tear Here

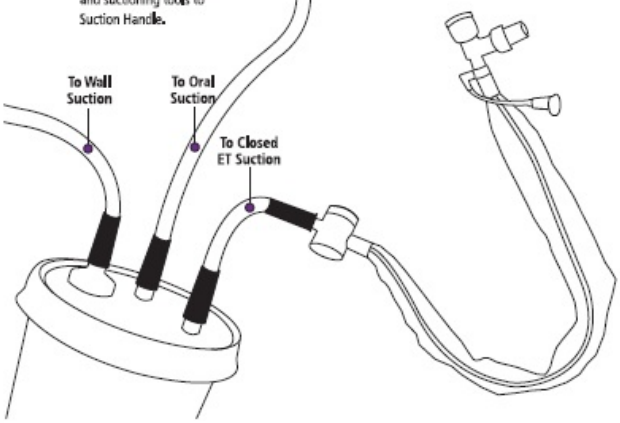
Q·Care® Rx Oral Cleansing & Suctioning System

with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse

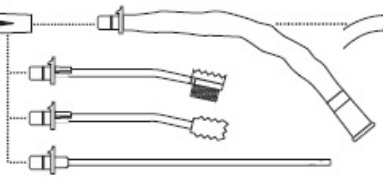
q4°

Setup Instructions: Multi-Port Canister

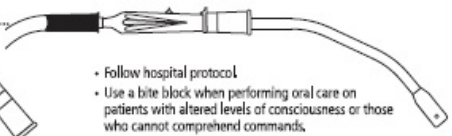
1. Connect tubing to suction port on canister. If additional port is needed, attach Y-Connector to suction port (see below*).
2. Connect the Suction Handle and Covered Yankauer to tubing.
3. Connecting tools: Detach the Covered Yankauer from Suction Handle. Attach cleansing and suctioning tools to Suction Handle.



Cleansing and Suctioning Tools attach to Suction Handle.



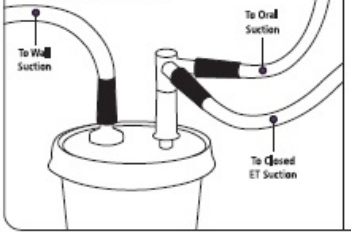
Using the Covered Yankauer to aid with removal of secretions:



- Follow hospital protocol.
- Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.
- Retract sleeve until cap locks in place.
- To suction, move switch to ON. When finished, move switch to OFF to prevent loss of suction power.
- Rinse after use until tubing is clear.
- Between uses, pull sleeve over tip to cover.
- Discard Yankauer and Y-Connector (if used) and Suction Handle after using for 24 hours, or according to hospital protocol.
- For single patient oral use.

*** Using Y-Connector**

- Use when additional suction port on canister is needed.



IMPORTANT: Both ports on Y-Connector must be utilized or a loss of suction power can occur.

Contents:

1 Suction Handle, Covered Yankauer and Y-Connector
2 Untreated Suction Toothbrush packages
2 Single dose bottles of 0.12% CHG Oral Rinse
4 Suction Oral Swab packages with Perox-A-Mint® Solution
2 Oropharyngeal Suction Catheter packages

Ingredients:

Perox-A-Mint® solution active ingredient: Hydrogen peroxide 1.5%
0.12% CHG Oral Rinse active ingredient: Chlorhexidine gluconate 0.12%
Kit also contains sodium bicarbonate and Mouth Moisturizer. For detailed listing of ingredients, see the enclosed individual packages.

Caution:

Federal (U.S.A.) law restricts this device (kit) to sale by or on the order of a physician or licensed practitioner.

Non-sterile • Latex free

MADE IN U.S.A.
Patents: www.sageproducts.com/patents

Reorder # 6904

6 18029 83008 1

SAGE® PRODUCTS

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

R4487B

Q-Care® Rx Oral Cleansing and Suctioning System, q4°

Suction Swab
with Perox-A-Mint® Solution

CONTENTS: 1 Suction Swab with sodium bicarbonate, .25 fl. oz./7ml Perox-A-Mint Solution, 0.07 oz./2g Mouth Moisturizer, 1 Applicator Swab

Drug Facts

Active ingredient	Purpose
PEROX-A-MINT: Hydrogen peroxide 1.5%	Oral debriding agent

Uses
- Aids in the removal of secretions and debris.

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 debriding 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.
- Remove Mouth Moisturizer and Applicator Swab.
- Attach Suction Swab to Suction Handle.
- Clean teeth and oral cavity for approximately one minute.
- To suction, slide switch to ON. When finished, return switch to OFF.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Suction Swab. Reattach Covered Yankauer to Suction Handle.
- Place Mouth Moisturizer on Applicator Swab.
- Apply as needed to lips and inside mouth.

- 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, menthol flavor, polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI 42090), Yellow 6 (CI 15985).

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.

Mouth Moisturizer ingredients*: Water (aqua), cocos nucifera (coconut) oil, xylitol, flavor (aroma), cellulose gum, tocopheryl acetate (vitamin E), mentha viridis (spearmint) leaf oil, carbomer, polysorbate 20, polysorbate 80, potassium sorbate, cetylpyridinium chloride.

* Manufactured for Sage Products LLC • Cary, IL

Patents: www.sageproducts.com/patents

LATEX FREE • FOR SINGLE USE ONLY • MADE IN U.S.A.

N 3 53462-075-60 5

Oral Check | Scan bar code for compliance to protocol

Suction Swab
with Perox-A-Mint® Solution

CONTENTS: 1 Suction Swab with sodium bicarbonate, .25 fl. oz./7ml Perox-A-Mint Solution, 0.07 oz./2g Mouth Moisturizer, 1 Applicator Swab

Drug Facts

Active ingredient	Purpose
PEROX-A-MINT: Hydrogen peroxide 1.5%	Oral debriding agent

Uses
- Aids in the removal of secretions and debris.

Warnings

Stop use and ask a doctor if:
- Sore mouth symptoms do not improve in 7 days.
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Keep out of reach of children.
If more than used for debriding 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.
- Remove Mouth Moisturizer and Applicator Swab.
- Attach Suction Swab to Suction Handle.
- Clean teeth and oral cavity for approximately one minute.
- To suction, slide switch to ON. When finished, return switch to OFF.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Suction Swab. Reattach Covered Yankauer to Suction Handle.
- Place Mouth Moisturizer on Applicator Swab.
- Apply as needed to lips and inside mouth.

- 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, menthol flavor, polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI 42090), Yellow 6 (CI 15985).

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

Mouth Moisturizer ingredients*: Water (aqua), cocos nucifera (coconut) oil, xylitol, flavor (aroma), cellulose gum, tocopheryl acetate (vitamin E), mentha viridis (spearmint) leaf oil, carbomer, polysorbate 20, polysorbate 80, potassium sorbate, cetylpyridinium chloride.

* Manufactured for Sage Products LLC • Cary, IL

Patents: www.sageproducts.com/patents

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N 3 53462-075-60 5

Oral Check | Scan bar code for compliance to protocol

Suction Toothbrush
CHG compatible*

CONTENTS: 1 Untreated Suction Toothbrush, 1 Untreated Swab, 0.5 fl. oz./15ml CHG Oral Rinse Active Ingredient: Chlorhexidine Gluconate 0.12%

***Compatible for use with 0.12% Chlorhexidine Gluconate (CHG) oral rinse, tested for use up to five minutes.**

NOTE: The following Uses and Directions refer to the Suction Toothbrush and Swab. For Warnings, Uses and Directions specific to the CHG rinse including use in children under 18 years of age, refer to that product's package insert and labeling.

Uses
- Aids in the removal of dental plaque, debris and secretions.

Directions
- Peel lid to open.
- Remove Suction Toothbrush and attach to Suction Handle.
- When using with a cleansing solution, refer to the product packaging for indications, instructions and warnings.
- To suction, slide switch to ON. When finished, return switch to OFF.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Suction Toothbrush. Reattach Covered Yankauer to Suction Handle.
- Use Swab for additional cleansing as needed.

- Use two 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.

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

Patents: www.sageproducts.com/patents

LATEX FREE • FOR SINGLE USE ONLY • MADE IN U.S.A.

Oropharyngeal Suction Catheter
Non-sterile

CONTENTS: 1 Suction Catheter

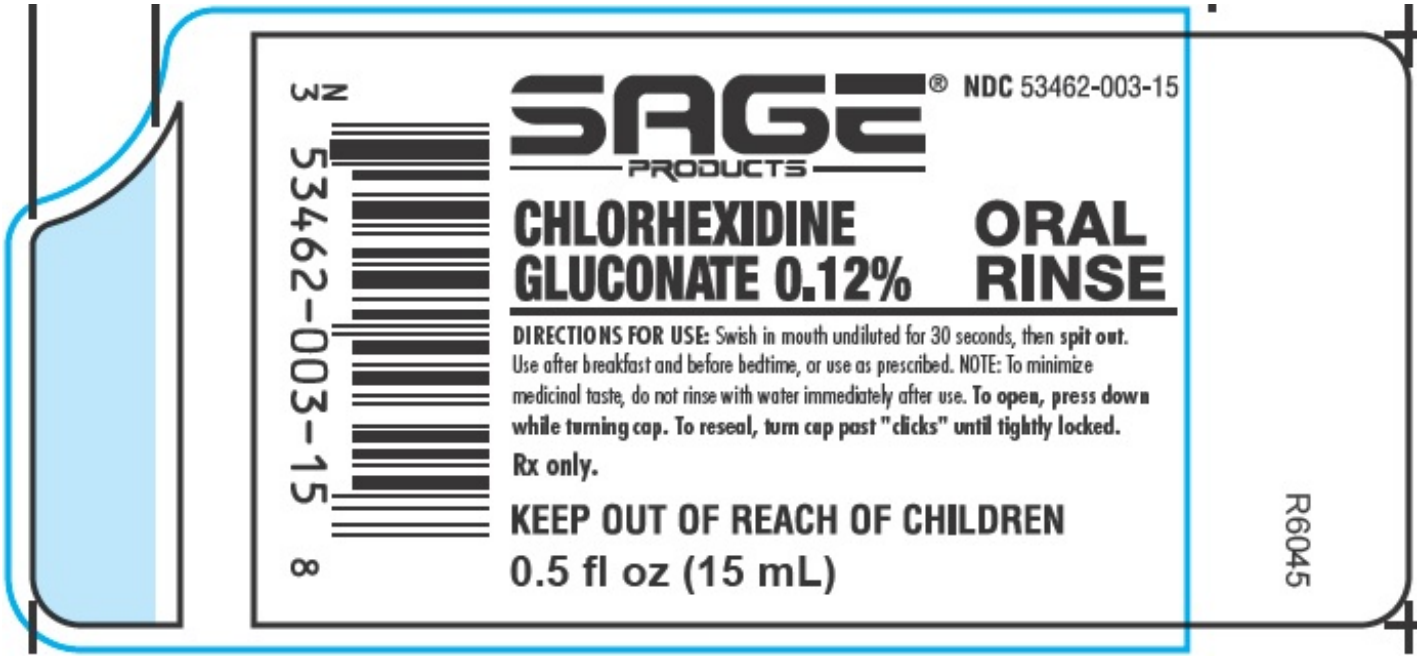
Uses
- Aids in the removal of secretions from the oropharyngeal cavity only.

Directions
- Peel lid to open.
- Attach Suction Catheter to Suction Handle.
- Suction secretions from the oropharyngeal cavity.
- To suction, slide switch to ON. When finished, return switch to OFF.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Suction Catheter. Reattach Covered Yankauer to Suction Handle.
- Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.

Caution
- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or licensed practitioner.

LATEX FREE • FOR SINGLE USE ONLY MADE IN U.S.A.

Chlorhexidine Gluconate 0.12% Label



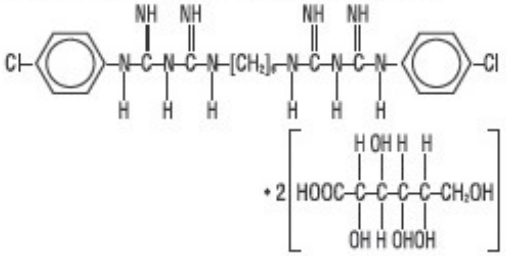
Chlorhexidine Gluconate 0.12% Insert

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:



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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 μg/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

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 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 1.0%. 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

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.

12.4688"

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: September, 2013

SAGE15ORBTLLBLB

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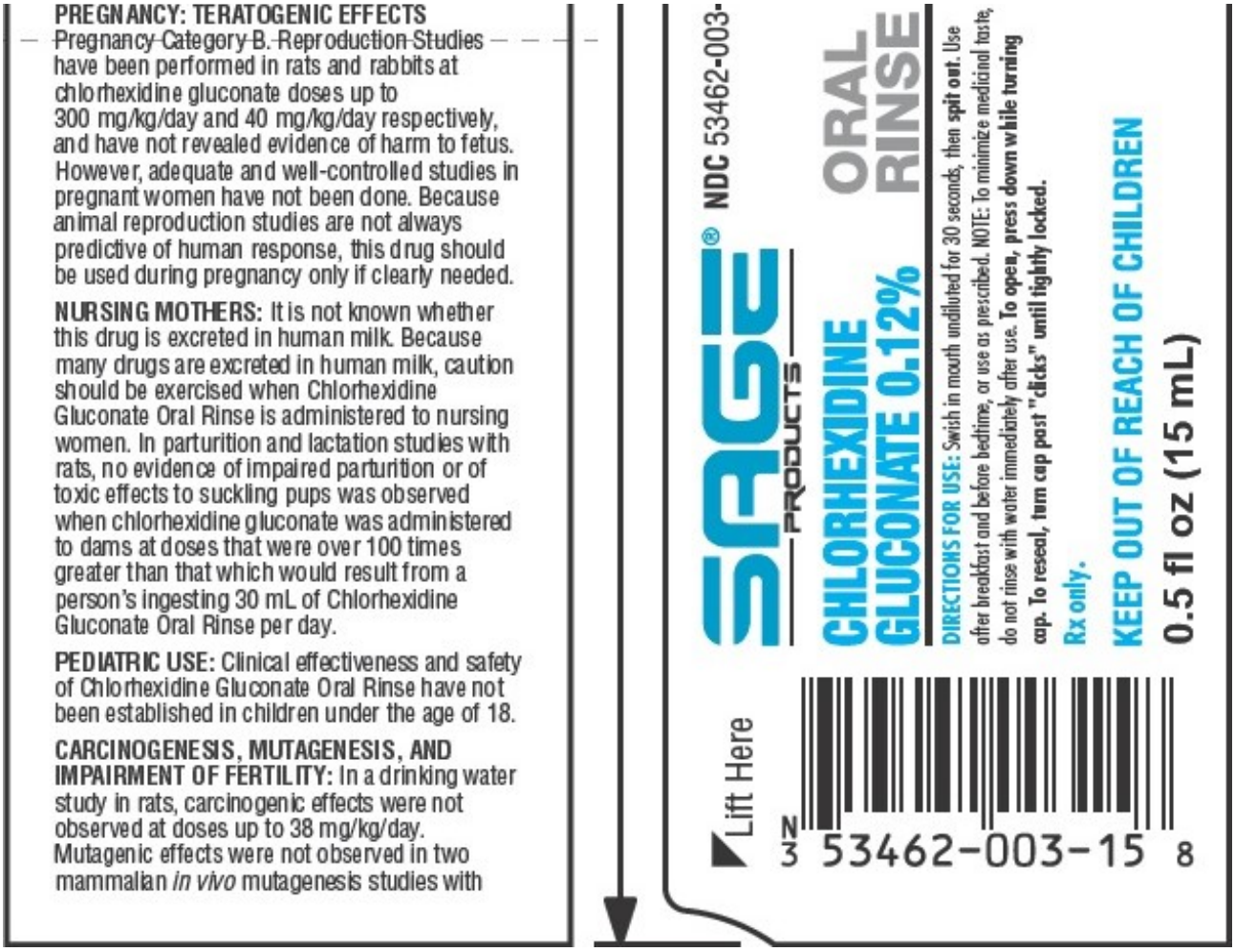

QCARE RX ORAL CLEANSING AND SUCTIONING SYSTEM, Q4

chlorhexidine gluconate and hydrogen peroxide kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53462-904

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53462-904-16	1 in 1 KIT		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	4 POUCH	28 mL in 4
Part 2	2 BOTTLE	30 mL in 2
Part 3		1
Part 4		2

Part 1 of 4

TOOTHETTE ORAL CARE SUCTION SWAB WITH PEROX-A-MINT SOLUTION

hydrogen peroxide mouthwash

Product Information	
Route of Administration	BUCCAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	15 [iU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		1 in 1 PACKAGE		
1		2 in 1 PACKET		
1		7 mL in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/21/1998	

Part 2 of 4

0.12% CHLORHEXIDINE GLUCONATE ORAL RINSE

chlorhexidine gluconate mouthwash

Product Information	
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 [iU] 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		15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077789	01/20/2014	

Part 3 of 4

SODIUM BICARBONATE

other oral hygiene products powder

Product Information	
Route of Administration	BUCCAL

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

MOUTH MOISTURIZER

other oral hygiene products emulsion

Product Information

Route of Administration	BUCCAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**COCONUT OIL** (UNII: Q9L0O73W7L)	
INGR	**XYLITOL** (UNII: VCQ006KQ1E)	
INGR	**CARBOXYMETHYLCELLULOSE SODIUM** (UNII: K679OBS311)	
INGR	**.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0)	
INGR	**WATER** (UNII: 059QF0KO0R)	
INGR	**POLYSORBATE 20** (UNII: 7T1F30V5YH)	
INGR	**POLYSORBATE 80** (UNII: 6OZP39ZG8H)	
INGR	**POTASSIUM SORBATE** (UNII: 1VPU26JZZ4)	
INGR	**CETYLPYRIDINIUM CHLORIDE** (UNII: D9OM4SK49P)	
INGR	**CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)** (UNII: HHT01ZNK31)	
INGR	**SPEARMINT OIL** (UNII: C3M81465G5)	

Marketing Information

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	12/31/2007	

Labeler - Sage Products LLC (054326178)

Registrant - Sage Products LLC (054326178)

Establishment

Name	Address	ID/FEI	Business Operations
Sage Products LLC		054326178	MANUFACTURE(53462-904)

Revised: 3/2014

Sage Products LLC