

ORAL CLEANSING AND SUCTIONING SYSTEM, Q2- 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.

Oral Cleansing and Suctioning System, q2

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.

Suction Swab with Alcohol-Free Mouthwash

- Aids in the removal of debris.
- Helps the mouth feel fresh and clean.
- Helps temporarily reduce dryness.

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 line.
- Clean teeth and oral cavity for approximately one minute.
- To suction, place thumb over port.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Suction Swab. Reattach Covered Yankauer to suction line.
- 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 line.
- 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 line.
- 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.

Suction Swab with Alcohol-Free Mouthwash

- **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 line.
- Clean teeth and oral cavity.
- To suction, place thumb over port.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Suction Swab. Reattach covered Yankauer to suction line.
- Place Mouth Moisturizer on Applicator Swab.
- Apply as needed to lips and inside mouth.
- Children under 12 years of age: supervise use.
- 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

- Attach Suction Catheter to suction line.
- Suction secretions from the oropharyngeal cavity.
- To suction, place thumb over port.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Suction Catheter. Reattach Covered Yankauer to suction line.
- 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)

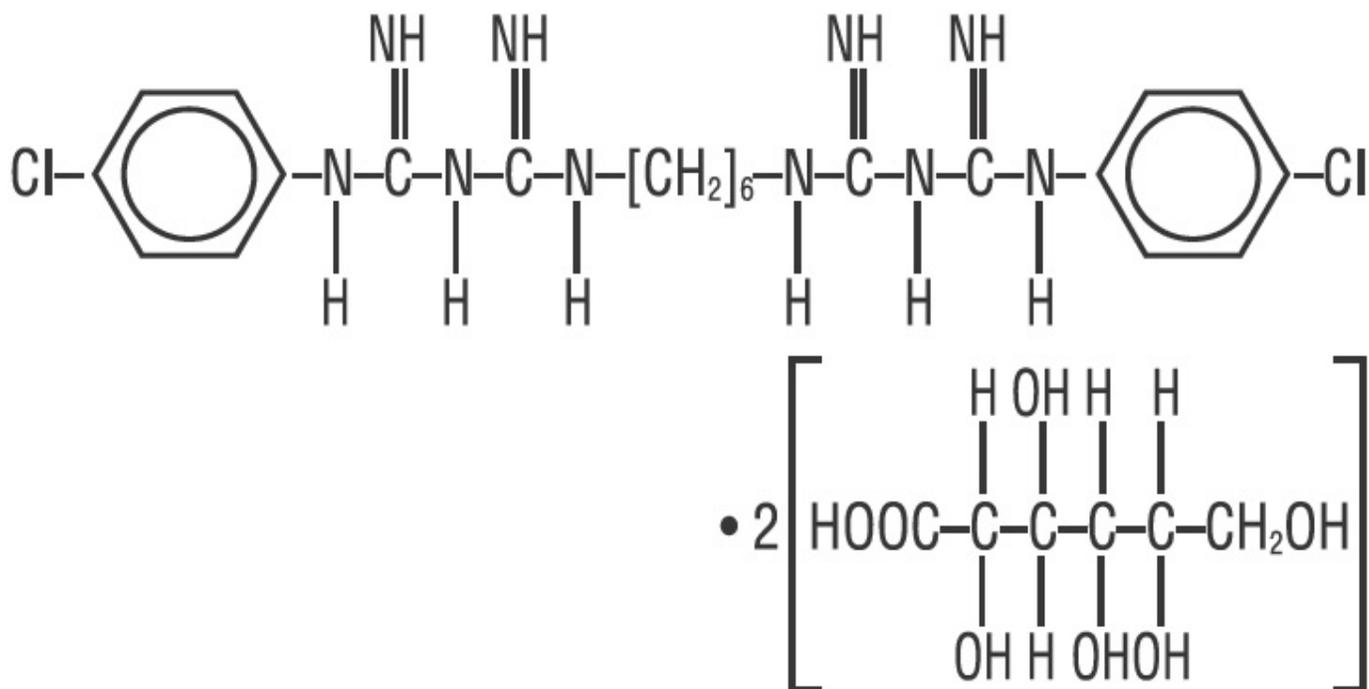
Questions?

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 (1,1¹-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 $\mu\text{g/g}$ 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

SAGE15ORBTLBLB

Oral Cleansing & Suctioning System with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse, q2
NDC: 53462-592-16

Oral Cleansing & Suctioning System

with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse



Setup Instructions: Multi-Port Canister

- 1 Connect tubing to suction port on canister.
- 2 Connect the Covered Yankauer to tubing.
- 3 Connecting tools: Detach the Covered Yankauer from tubing. Attach cleansing and suctioning tools directly to tubing.

Cleansing and Suctioning Tools attach directly to standard suction lines.

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 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 Covered Yankauer and Y-Connector
- 2 Untreated Suction Toothbrush packages
- 2 Single dose bottles of 0.12% CHG Oral Rinse
- 4 packages Suction Oral Swabs with sodium bicarbonate, Perox-A-Mint® solution and Mouth Moisturizer
- 6 packages Suction Oral Swabs with sodium bicarbonate, Alcohol-free Mouthwash and Mouth Moisturizer
- 2 Oropharyngeal Suction Catheter packages

Ingredients:

Perox-A-Mint® solution (active ingredient: Hydrogen peroxide 1.5%)
CHG Oral Rinse (active ingredient: Chlorhexidine gluconate 0.12%)
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 # 6592



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

Chlorhexidine Gluconate 0.12% Oral Rinse- Label

TOOTHEITE[®] Oral Care
Suction Swab
 with Perox-A-Mint[®] Solution

Peel Here

CONTENTS: 1 Suction Swab with sodium bicarbonate, 0.25 fl.oz./7ml Perox-A-Mint Solution, 0.07 oz./2g Mouth Moisturizer, 1 Unreated Applicator Swab

Drug Facts

Active Ingredient
 Perox-A-Mint:
 Hydrogen peroxide 1.5%,.....Oral debriding agent

Purpose
 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 thumb.
 • Peel lid to open.
 • Remove Mouth Moisturizer and Applicator Swab.
 • Attach Suction Swab to suction line.
 • Clean suction and oral cavity for approximately one minute.
 • To suction, place thumb over port.
 • To clear tubing, rinse with sterile saline or appropriate solution.
 • Discard Suction Swab. Reattach Covered Yehauser to suction line.
 • 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, mentho flavor, polyorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI 42090), Yellow 6 (CI 15985).

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

Sodium Bicarbonate Ingredients: Water (liquid), sodium bicarbonate, calcium gum, sodium alanyl sulfinate, lauryl (arabic), polyorbate 80, polyorbate 20, polyorbate 30, polyorbate 40, polyorbate 50, polyorbate 60, polyorbate 70, polyorbate 80, polyorbate 90, polyorbate 100, polyorbate 110, polyorbate 120, polyorbate 130, polyorbate 140, polyorbate 150, polyorbate 160, polyorbate 170, polyorbate 180, polyorbate 190, polyorbate 200, polyorbate 210, polyorbate 220, polyorbate 230, polyorbate 240, polyorbate 250, polyorbate 260, polyorbate 270, polyorbate 280, polyorbate 290, polyorbate 300, polyorbate 310, polyorbate 320, polyorbate 330, polyorbate 340, polyorbate 350, polyorbate 360, polyorbate 370, polyorbate 380, polyorbate 390, polyorbate 400, polyorbate 410, polyorbate 420, polyorbate 430, polyorbate 440, polyorbate 450, polyorbate 460, polyorbate 470, polyorbate 480, polyorbate 490, polyorbate 500, polyorbate 510, polyorbate 520, polyorbate 530, polyorbate 540, polyorbate 550, polyorbate 560, polyorbate 570, polyorbate 580, polyorbate 590, polyorbate 600, polyorbate 610, polyorbate 620, polyorbate 630, polyorbate 640, polyorbate 650, polyorbate 660, polyorbate 670, polyorbate 680, polyorbate 690, polyorbate 700, polyorbate 710, polyorbate 720, polyorbate 730, polyorbate 740, polyorbate 750, polyorbate 760, polyorbate 770, polyorbate 780, polyorbate 790, polyorbate 800, polyorbate 810, polyorbate 820, polyorbate 830, polyorbate 840, polyorbate 850, polyorbate 860, polyorbate 870, polyorbate 880, polyorbate 890, polyorbate 900, polyorbate 910, polyorbate 920, polyorbate 930, polyorbate 940, polyorbate 950, polyorbate 960, polyorbate 970, polyorbate 980, polyorbate 990, polyorbate 1000.

Latex Free • PFR SINGLE USE ONLY • MADE IN U.S.A.
 Manufactured for Sage Products LLC • Cary, IL
 Patients: www.sageproducts.com/patients

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

6 18029 00002 6

Toothette Oral Care Suction Toothbrush, CHG Compatible - Label

TOOTHEITE[®] Oral Care
Suction Toothbrush
 CHG compatible[®]

Peel Here

CONTENTS: 1 Unreated Suction Toothbrush, 1 Unreated Swab

*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 line.
 • 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 Yehauser to suction line.
 • 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.

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ORAL CLEANSING AND SUCTIONING SYSTEM, Q2

chlorhexidine gluconate and hydrogen peroxide kit

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:53462-592

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-592-16	1 in 1 KIT; Type 1: Convenience Kit of Co-Package		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		10 in 10
Part 2	10 POUCH	20 g in 10
Part 3	6 POUCH	42 mL in 6
Part 4	4 POUCH	112 mL in 4
Part 5	2 BOTTLE	30 mL in 2

Part 1 of 5

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 2 of 5

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	CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
INGR	CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
INGR	SPEARMINT OIL (UNII: C3M81465G5)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 g in 1 POUCH		

Marketing Information

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

Part 3 of 5

TOOTHETTE ORAL CARE SUCTION SWAB WITH ALCOHOL-FREE MOUTHWASH

dentifrices (aerosol, liquid, pastes, and powders) mouthwash

Product Information

Route of Administration	BUCCAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	SORBITOL (UNII: 506T60A25R)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
INGR	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7 mL in 1 POUCH		

Marketing Information

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

Part 4 of 5

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: 059QF0K00R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		28 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 5 of 5

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 -	CHLORHEXIDINE	1.2 [iU]

UNII:R4KO0DY52L)		GLUCONATE	in 1 mL	
Inactive Ingredients				
Ingredient Name				Strength
GLYCERIN (UNII: PDC6A3C0OX)				
PEG-40 SORBITAN DIISOSTEARATE (UNII: JL4CCU7IIG)				
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	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part356		07/01/2014	

Labeler - Sage Products LLC (054326178)

Registrant - Sage Products LLC (054326178)

Establishment

Name	Address	ID/FEI	Business Operations
Sage Products LLC		054326178	MANUFACTURE(53462-592)