

QCARE RX ORAL CLEANSING AND SUCTIONING SYSTEM- chlorhexidine gluconate and cetylpyridinium chloride
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 & Suctioning System featuring Corinz™ Antiseptic Cleansing and Moisturizing Oral Rinse and 0.12% chlorhexidine gluconate oral rinse

Drug Facts

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

Uses

Suction Swab with Corinz Antiseptic Cleansing and Moisturizing Oral Rinse

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

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

Directions

Suction Swab with Corinz Antiseptic Cleansing and Moisturizing Oral Rinse

- **Before opening**, turn package over, burst solution packet with thumbs.
- Peel lid to open.
- 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.

- 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.

Oropharyngeal Suction Catheter Non-sterile

- Peel lid to open.
- 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 Corinz Antiseptic Cleansing and Moisturizing Oral Rinse

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

Questions?

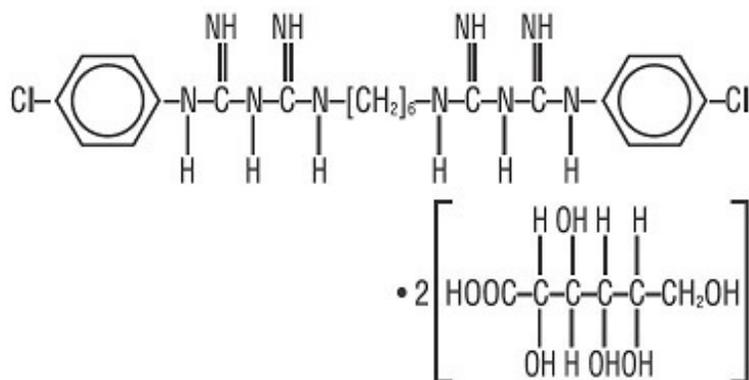
Call toll-free 800-323-2220.

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

CHLORHEXIDINE GLUCONATE ORAL RINSE, 0.12%

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

Corinz Label



SAGE
PRODUCTS

Q-Care[®]
Oral Cleansing & Suctioning System
with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse

FEATURING
Corinz[™]
Antibiotic Cleansing & Moisturizing O-Rinse

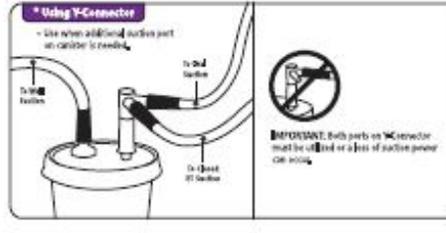
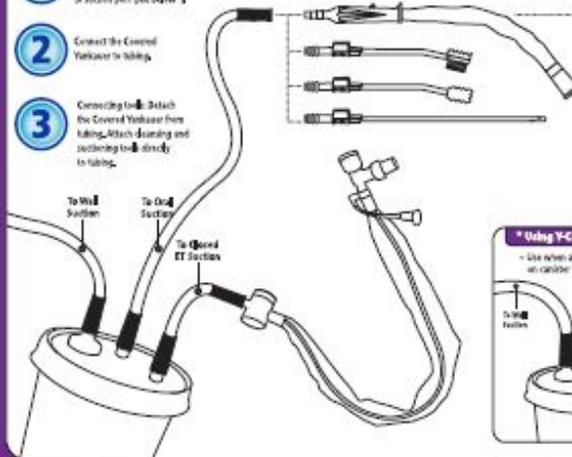
Setup Instructions: Multi-Port Canister

- 1** Connect tubing to suction part on canister. If additional part is needed, attach W-Connector to suction part (see below).
- 2** Connect the Covered Yankauer to tubing.
- 3** Connecting to Detail: Detach the Covered Yankauer from tubing. Attach deaerating and suctioning tool 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.
- **Restart device and setup tools in place.**
- To suction, make switch to ON. When finished, move switch to OFF to prevent loss of suction power.
- **Wipe after use with tubing in ON.**
- **Between uses, pull down cover cap to cover.**
- **Discard Yankauer and W-Connector if used after using for 24 hours, or according to hospital protocol.**
- **For single-patient use only.**



Contents:

- 1 Covered Yankauer and W-Connector
- 2 Unwrapped Suction Tool(s) in package
- 3 SAGE Oral Rinse (0.12% CHG Oral Rinse)
- 4 Suction Tool Rinse package with Corinz[™] Antibiotic Cleansing and Moisturizing Oral Rinse
- 5 Disposable Suction Canister package

Ingredients:

CHG Oral Rinse active ingredient: Chlorhexidine gluconate 0.12%

Corinz[™] Antibiotic Cleansing and Moisturizing Oral Rinse Active Ingredient: Cetylpyridinium chloride 0.05%

It also contains various bioactives. For detailed listing of ingredients, see the enclosed individual packages.

Caution:

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

Non-sterile • Latex free

Reorder # 6964



SAGE
PRODUCTS

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3509 Three Oaks Road | Cary, Illinois 60013
www.sageproducts.com | 800-828-2220

MADE IN CHINA
Patents: sageproducts.com/patents

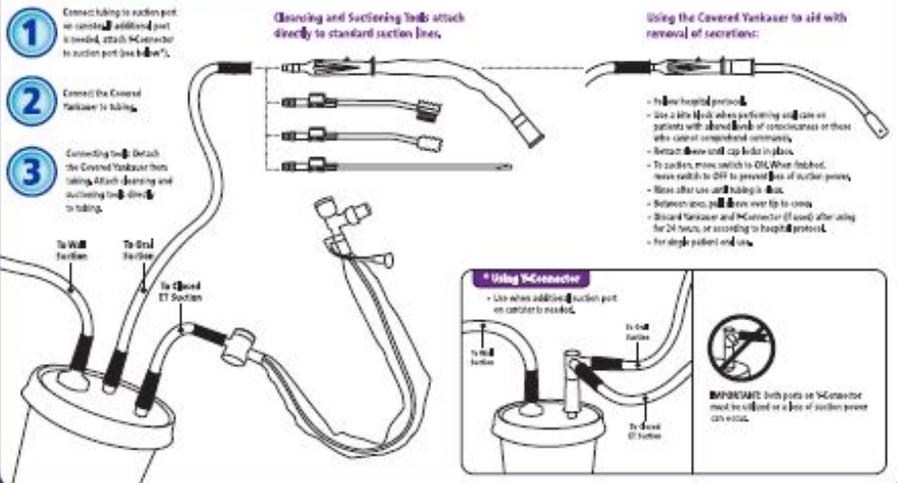
QCARE RX ORAL CLEANSING AND SUCTIONING SYSTEM

SAGE PRODUCTS

Q-Care^{rx} Oral Cleansing & Suctioning System with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse

CorinzTM Antiseptic Cleansing & Maintaining Oral Rinse

Setup Instructions: Multi-Port Canister



Contents: 1 Covered Yankasser and Y-Connector, 2 Suctioning Tubing Packages, 3 High Absorbency 0.12% CHG Oral Rinse, 4 Suction Canister, 5 CorinzTM Antiseptic Cleansing and Maintaining Oral Rinse, 6 Sterile Yankasser Suction Canister Package. Ingredients: CHG Oral Rinse Active Ingredient: Chlorhexidine gluconate 0.12%. CorinzTM Antiseptic Cleansing and Maintaining Oral Rinse Active Ingredients: Combination of 0.12% CHG. Also contains sodium bicarbonate. For detailed listing of ingredients, see the enclosed instruction packages. Caution: Federal (FDA) law restricts this device (DR) to sale by or on the order of a physician or dentist. Non-sterile - Latex free.

Reorder # 6962

SAGE PRODUCTS Sage Products LLC 2309 Three Oaks Road | Cary, North Carolina 27513 www.sageproducts.com | 800-323-2220



SUCTION SWAB with CorinzTM Antiseptic Cleansing & Maintaining Oral Rinse. Contains 1 Suction Swab with saline treatment, 1 1/2 CorinzTM Antiseptic Cleansing and Maintaining Oral Rinse. Drug Facts: Active Ingredient: CORINZTM ANTISEPTIC CLEANSING AND MAINTAINING ORAL RINSE. Purpose: Antiseptic Rinse. Use: Add to the removal of secretions and debris and help reduce the chance of infection in oral cavity. Warnings: Stop use and ask a doctor if symptoms persist or worsen. Directions: Before opening, turn package over, burst within 10 seconds. Use up to 4 times daily or as directed by a dentist or doctor.

SUCTION SWAB with CorinzTM Antiseptic Cleansing & Maintaining Oral Rinse. Contains 1 Suction Swab with saline treatment, 1 1/2 CorinzTM Antiseptic Cleansing and Maintaining Oral Rinse. Drug Facts: Active Ingredient: CORINZTM ANTISEPTIC CLEANSING AND MAINTAINING ORAL RINSE. Purpose: Antiseptic Rinse. Use: Add to the removal of secretions and debris and help reduce the chance of infection in oral cavity. Warnings: Stop use and ask a doctor if symptoms persist or worsen. Directions: Before opening, turn package over, burst within 10 seconds. Use up to 4 times daily or as directed by a dentist or doctor.

SUCTION SWAB with CorinzTM Antiseptic Cleansing & Maintaining Oral Rinse. Contains 1 Suction Swab with saline treatment, 1 1/2 CorinzTM Antiseptic Cleansing and Maintaining Oral Rinse. Drug Facts: Active Ingredient: CORINZTM ANTISEPTIC CLEANSING AND MAINTAINING ORAL RINSE. Purpose: Antiseptic Rinse. Use: Add to the removal of secretions and debris and help reduce the chance of infection in oral cavity. Warnings: Stop use and ask a doctor if symptoms persist or worsen. Directions: Before opening, turn package over, burst within 10 seconds. Use up to 4 times daily or as directed by a dentist or doctor.

OROPHARYNGEAL SUCTION CATHETER Non-sterile. Contains 1 Suction Catheter. Drug Facts: Active Ingredient: Suction Catheter. Purpose: Suctioning. Use: Add to the removal of secretions from the oropharyngeal cavity. Warnings: Stop use and ask a doctor if symptoms persist or worsen. Directions: Before opening, turn package over, burst within 10 seconds. Use up to 4 times daily or as directed by a dentist or doctor.

SUCTION SWAB with CorinzTM Antiseptic Cleansing & Maintaining Oral Rinse. Contains 1 Suction Swab with saline treatment, 1 1/2 CorinzTM Antiseptic Cleansing and Maintaining Oral Rinse. Drug Facts: Active Ingredient: CORINZTM ANTISEPTIC CLEANSING AND MAINTAINING ORAL RINSE. Purpose: Antiseptic Rinse. Use: Add to the removal of secretions and debris and help reduce the chance of infection in oral cavity. Warnings: Stop use and ask a doctor if symptoms persist or worsen. Directions: Before opening, turn package over, burst within 10 seconds. Use up to 4 times daily or as directed by a dentist or doctor.

SUCTION SWAB with CorinzTM Antiseptic Cleansing & Maintaining Oral Rinse. Contains 1 Suction Swab with saline treatment, 1 1/2 CorinzTM Antiseptic Cleansing and Maintaining Oral Rinse. Drug Facts: Active Ingredient: CORINZTM ANTISEPTIC CLEANSING AND MAINTAINING ORAL RINSE. Purpose: Antiseptic Rinse. Use: Add to the removal of secretions and debris and help reduce the chance of infection in oral cavity. Warnings: Stop use and ask a doctor if symptoms persist or worsen. Directions: Before opening, turn package over, burst within 10 seconds. Use up to 4 times daily or as directed by a dentist or doctor.

SUCTION TOOTHBRUSH CHG compatible. Contains 1 Suction Toothbrush in Foam, 1 Suction Swab, 1 1/2 CorinzTM Antiseptic Cleansing and Maintaining Oral Rinse. Drug Facts: Active Ingredient: Suction Toothbrush. Purpose: Suctioning. Use: Add to the removal of secretions from the oropharyngeal cavity. Warnings: Stop use and ask a doctor if symptoms persist or worsen. Directions: Before opening, turn package over, burst within 10 seconds. Use up to 4 times daily or as directed by a dentist or doctor.

OROPHARYNGEAL SUCTION CATHETER Non-sterile. Contains 1 Suction Catheter. Drug Facts: Active Ingredient: Suction Catheter. Purpose: Suctioning. Use: Add to the removal of secretions from the oropharyngeal cavity. Warnings: Stop use and ask a doctor if symptoms persist or worsen. Directions: Before opening, turn package over, burst within 10 seconds. Use up to 4 times daily or as directed by a dentist or doctor.

0.12% Chlorhexidine Gluconate Oral Rinse Label

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 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 [iU] 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; 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	

Part 3 of 3

CORINZ

cetylpyridinium chloride rinse

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7J10JV3)	CETYLPYRIDINIUM CHLORIDE	.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HYDROXYETHYL CELLULOSE (4000 MPAS AT 1%) (UNII: ZYD53NBL45)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 PACKET		
1		7 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/11/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/11/2016	

QCARE RX ORAL CLEANSING AND SUCTIONING SYSTEM

chlorhexidine gluconate and cetylpyridinium chloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53462-962
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-962-16	1 in 1 KIT; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug	01/11/2016	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		1
Part 2	2 BOTTLE	30 mL in 2
Part 3	10 POUCH	70 mL in 10

Part 1 of 3

SODIUM BICARBONATE

other oral hygiene products powder

Product Information

Route of Administration	BUCCAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
INGR	CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	

INGR	SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	WATER (UNII: 059QF0K00R)	
INGR	SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Marketing Information

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

Part 2 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 [iU] 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: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

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

Part 3 of 3

CORINZ

cetylpyridinium chloride rinse

Product Information

Item Code (Source) NDC:53462-375

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYL PYRIDINIUM - UNII: CUB7J10JV3)	CETYL PYRIDINIUM CHLORIDE	.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HYDROXYETHYL CELLULOSE (4000 MPAS AT 1%) (UNII: ZYD53NBL45)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 PACKET		
1		7 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/11/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final	part356	01/11/2016	
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Labeler - Sage Products LLC (054326178)

Registrant - Sage Products LLC (054326178)

Establishment

Name	Address	ID/FEI	Business Operations
Sage Products LLC		054326178	MANUFACTURE(53462-964, 53462-962, 53462-375)

Revised: 2/2016

Sage Products LLC