# QCARE ORAL CLEANSING AND SUCTIONING SYSTEM COMPATIBLE WITH 0.12% CHLORHEXIDINE GLUCONATE (CHG) ORAL RINSE- cetylpyridinium chloride
## Sage Products LLC

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**QCare Oral Cleansing & Suctioning System compatible with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse**

*Drug Facts*

### Suction Swab with Antiseptic Oral Rinse

| *Active Ingredient:* | *Purpose* |
|---|---|
| Corinz™ Antiseptic Cleansing and Moisturizing Oral Rinse:<br>Cetylpyridinium chloride 0.05% | Antiseptic Rinse |

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

*Directions*

**Suction Swab with Antiseptic Oral Rinse**

**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 suctions, 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

NOT MADE WITH NATURAL RUBBER LATEX • FOR SINGLE USE ONLY • MADE IN U.S.A.

**Manufactured for:**
Sage Products LLC
Cary, IL 60013

1-800-323-2220


**QCare Oral Cleansing & Suctioning System compatible with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse**

# SAGE® PRODUCTS

## Q·Care®

FEATURING **Corinz**™
Antiseptic Cleansing & Moisturizing Oral Rinse

### Oral Cleansing & Suctioning System
compatible with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse

## 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*).
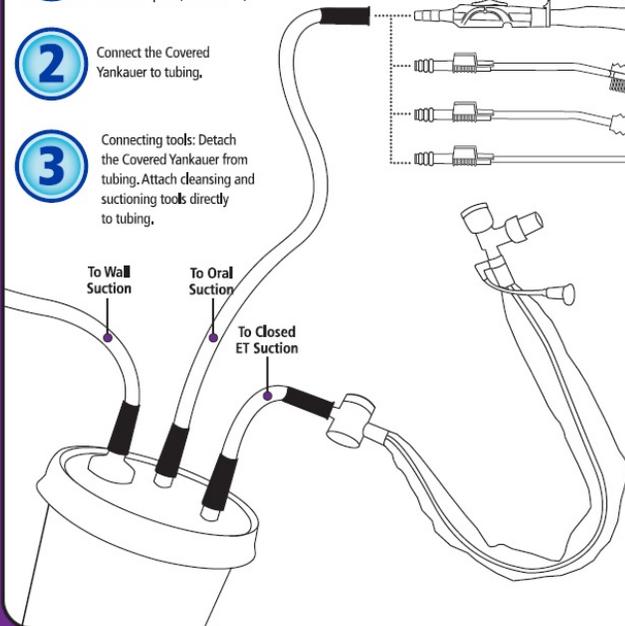
**2** Connect the Covered Yankauer to tubing.

**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.
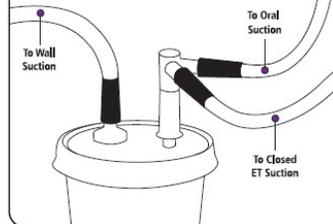
To Wall Suction
To Oral Suction
To Closed ET Suction

**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) 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.

To Wall Suction
To Oral Suction
To Closed ET Suction

**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
**4** Suction Oral Swab packages with Corinz™ Antiseptic Cleansing and Moisturizing Oral Rinse
**2** Oropharyngeal Suction Catheter packages

## Ingredients:
**Corinz™ Antiseptic Cleansing and Moisturizing Oral Rinse Active Ingredient:**
Cetylpyridinium chloride 0.05%
Kit also contains sodium bicarbonate. 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 • Not made with natural rubber latex**

### Reorder # 6994

6 18029 83094 4

## SAGE® PRODUCTS
Sage Products LLC
3909 Three Oaks Road | Cary, Illinois 60013
www.sageproducts.com | 800-323-2220

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

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# SAGE® PRODUCTS

## Q·Care® Rx
Oral Cleansing & Suctioning System

FEATURING **Corinz**™
Antiseptic Cleansing & Moisturizing Oral Rinse

Reorder #6994

DATE

**STEP 6**

— — — : — —
TIME FOR CARE

3 53462 37560 6

SCAN TO TRACK

**STEP 5**

TIME FOR CARE

SCAN TO TRACK

3 53462 37560 6

**STEP 4**

TIME FOR CARE

# SAGE®
## PRODUCTS

*Q·Care* Rx
**Oral Cleansing & Suctioning System**

**Corinz™**
FEATURING
Antiseptic Cleansing &
Moisturizing Oral Rinse

Reorder #6994

DATE

**STEP 3**

TIME FOR CARE

SCAN TO TRACK

3 53462 37560 6

**STEP 2**

TIME FOR CARE

SCAN TO TRACK
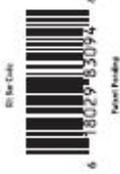
3 53462 37560 6

**STEP 1**

TIME FOR CARE

## SUCTION SWAB
with Corinz™ Antiseptic Cleansing & Moisturizing Oral Rinse

CONTENTS: 1 Suction Swab with sodium bicarbonate, 0.25 fl oz/7ml Corinz Antiseptic Cleansing and Moisturizing Oral Rinse

### Drug Facts

**Active Ingredient** — **Purpose**
CORINZ ANTISEPTIC CLEANSING AND MOISTURIZING ORAL RINSE
Cetylpyridinium chloride 0.05% .... Antiseptic Rinse

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

**Warnings**
Stop use and ask a doctor if:
- Sore mouth symptoms do not improve in 7 days.
- Swelling, rash or fever develops.
- Irritation, pain or redness persists or worsens.

Keep out of reach of children.
If more than used for antisepsis is accidentally swallowed, get medical help or contact a Poison Control Center right away.

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

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

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

Sodium Bicarbonate Ingredients: Water, sodium bicarbonate, sodium carboxymethylcellulose, sodium benzoate, flavor, sodium saccharin, sodium benzoate.

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## SUCTION SWAB
with Corinz™ Antiseptic Cleansing & Moisturizing Oral Rinse

CONTENTS: 1 Suction Swab with sodium bicarbonate, 0.25 fl oz/7ml Corinz Antiseptic Cleansing and Moisturizing Oral Rinse

### Drug Facts

**Active Ingredient** — **Purpose**
CORINZ ANTISEPTIC CLEANSING AND MOISTURIZING ORAL RINSE
Cetylpyridinium chloride 0.05% .... Antiseptic Rinse

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

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

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

Sodium Bicarbonate Ingredients: Water, sodium bicarbonate, sodium carboxymethylcellulose, sodium benzoate, flavor, sodium saccharin, sodium benzoate.

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## SUCTION TOOTHBRUSH
CHG compatible*

CONTENTS: 1 Untreated Suction Toothbrush, 1 Untreated 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 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.

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

Patent: www.sageproducts.com/patents

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## OROPHARYNGEAL SUCTION CATHETER
Nonsterile

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 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.

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

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**Corinz Label**

## QCARE ORAL CLEANSING AND SUCTIONING SYSTEM COMPATIBLE WITH 0.12% CHLORHEXIDINE GLUCONATE (CHG) ORAL RINSE

cetylpyridinium chloride kit

### Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53462-994 |
|---|---|---|---|

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | NDC:53462-994-60 | 1 in 1 KIT; Type 1: Convenience Kit of Co-Package | 11/16/2016 | |

### Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|---|---|---|
| Part 1 | 4 PACKET | 28 mL in 2 |
| Part 2 | | 1 |

## Part 1 of 2

## 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:CUB7JI0JV3) | CETYLPYRIDINIUM CHLORIDE | 0.5 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 MPA.S 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 PACKET; Type 1: Convenience Kit of Co-Package | | |

## Marketing Information

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

## Part 2 of 2

# 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 | | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part356 | 11/16/2016 | |

**Labeler -** Sage Products LLC (054326178)

**Registrant -** Sage Products LLC (054326178)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Sage Products LLC | | 054326178 | manufacture(53462-994, 53462-375) |

Revised: 10/2019

Sage Products LLC