QCARE ORAL CLEANSING AND SUCTIONING SYSTEM COMPATIBLE WITH 0.12% CHLORHEXIDINE GLUCONATE (CHG) ORAL RINSE- 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 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	Antiseptic
Rinse:	Rinse
Cetylpyridinium chloride 0.05%	

*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.

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





FEATURING

Oral Cleansing & Suctioning System

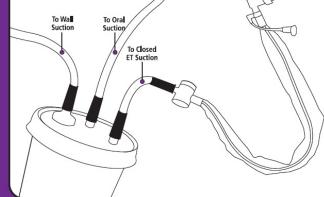
compatible with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse

Setup Instructions: Multi-Port Canister



Connect the Covered Yankauer to tubing.

Connecting tools: Detach the Covered Yankauer from tubing. Attach cleansing and suctioning tools directly to tubing.



Cleansing and Suctioning Tools attach

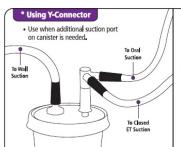
directly to standard suction lines.

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Using the Covered Yankauer to aid with removal of secretions:



- 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 dear.
- · 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.





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

Contents:

- Covered Yankauer and Y-Connector
 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:
Ceylpyridinium 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





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



MADE IN U.S.A.

Oral Cleansing & Suctioning System



Reorder #6994

DATE







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SUCTION SWAB

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Drug Facts

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SUCTION **TOOTHBRUSH**

CHG compatible*

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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	
ı	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

ı	Active Ingredient/Active Moiety		
	Ingredient Name	Basis of Strength	Strength
	CETYLPYRIDINIUM CHLO RIDE (UNII: D9 OM4SK49 P) (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 MO NO HYDRATE (UNII: 2968 PHW8 QP)	
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			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
part356	0 1/11/20 16		
	Application Number or Monograph Citation	Application Number or Monograph Citation Marketing Start Date	

Part 2 of 2

SODIUM BICARBONATE

other oral hygiene products powder

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Route of Administration BUCCAL

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Ingredient Kind	Ingredient Name	Quantity

INGR	SODIUM BICARBONATE (UNII: 8 MDF5 V39 QO)
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 Infor	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