QCARE ORAL CLEANSING AND SUCTIONING SYSTEM- 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 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.

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

Toothette Oral Care Suction Toothbrush
- **Before opening,** turn package over, burst solution packet with thumbs.
- Peel lid to open.
- Attach Toothbrush 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 Toothbrush. 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.

Toothette Oral Care Suction Swab

- **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.

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 Yankaurer to suction line.
- Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.

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.

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

Corinz Label

Corinz™
Antiseptic Cleansing &
Moisturizing Oral Rinse
Active Ingredient:
Cetylpyridinium
chloride 0.05%
Squeeze Here
To Release Fluid
BURST PACKET
BEFORE OPENING
OUTER PACKAGE
Do not remove
from package
0.25 fl. oz./7 mL
RS439

Corinz™
Antiseptic Cleansing &
Moisturizing Oral Rinse
Active Ingredient:
Cetylpyridinium
chloride 0.05%
Squeeze Here
To Release Fluid
BURST PACKET
BEFORE OPENING
OUTER PACKAGE
Do not remove
from package
0.25 fl. oz./7 mL
101

QCARE ORAL CLEANSING AND SUCTIONING SYSTEM

SAGE® PRODUCTS

Q·Care®

Oral Cleansing & Suctioning System

FEATURING **Corinz™** Antiseptic Cleansing & Moisturizing 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*).
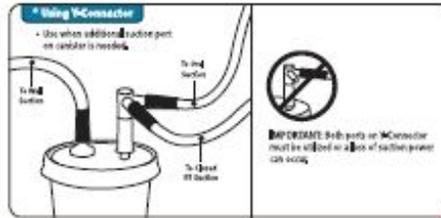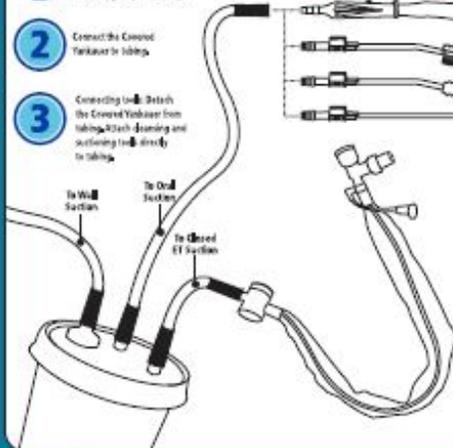
2 Connect the Covered Yankauer to tubing.

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

To Wall Suction
To Oral Suction
To Closed ET Suction

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 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 Suction Toothbrush packages with with Corinz™ Antiseptic Cleansing and Moisturizing Oral Rinse
10 Suction Oral Swab packages with with Corinz™ Antiseptic Cleansing and Moisturizing Oral Rinse
4 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 • Latex free

Reorder # 6462

QCARE ORAL CLEANSING AND SUCTIONING SYSTEM
cetylpyridinium chloride kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53462-462

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-462-60	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	12 POUCH	84 mL in 12

Part 1 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			

Part 2 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	.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		12 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 ORAL CLEANSING AND SUCTIONING SYSTEM
cetylpyridinium chloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53462-464

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-464-60	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	6 POUCH	42 mL in 6

Part 1 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			

Part 2 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	.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		6 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	

Labeler - Sage Products LLC (054326178)

Registrant - Sage Products LLC (054326178)

Establishment

Name	Address	ID/FEI	Business Operations

| Sage Products LLC | | 054326178 | MANUFACTURE(53462-464, 53462-375, 53462-462) |