

QCARE ORAL CLEANSING AND SUCTIONING SYSTEM, Q4- cetylpyridinium chloride 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.

QCare Oral Cleansing and Suctioning System, Q4

Drug Facts

Active Ingredient: PEROX-A-MINT: Hydrogen Peroxide 1.5%	Purpose Oral Debriding Agent
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Active Ingredient: ANTIPLAQUE*: Cetylpyridinium chloride .05%	Purpose Antigingivitis/antiplaque
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USES

Suction Swab with Perox-A-Mint Solution:

- Aids in the removal of secretions and debris.

Suction Toothbrush with Antiplaque Solution:

- Aids in the removal and prevention of plaque that leads to gingivitis.

WARNINGS

Suction Swab with Perox-A-Mint Solution:

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.

Suction Toothbrush with Antiplaque Solution:

Stop use and ask a dentist if:

- Gingivitis, bleeding or redness persists for more than 2 weeks.
- You have painful or swollen gums, pus from the gum line, loose teeth or increasing spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.

Suction Swab with Perox-A-Mint Solution:

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.

Suction Toothbrush with Antiplaque Solution:

Keep out of reach of children under 6 years of age

If more than used for brushing 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 with Antiplaque Solution:

- **Before opening**, turn package over, burst solution packet with thumbs.
- Peel lid to open.
- Remove Mouth Moisturizer and Applicator Swab.
- 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.
- Place Mouth Moisturizer on Applicator Swab.
- Apply as needed to lips and inside mouth.
- Adults and children 12 years of age and older: use two times daily or as directed by a dentist. Do not swallow the solution.
- Children ages 6 to 12 years: supervise use.
- Children under 6 years of age: do not 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.

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)

Suction Toothbrush with Antiplaque Solution:

Water, sorbitol, peppermint flavor, potassium sorbate, polysorbate 80, polysorbate 20, citric acid, Blue 1 (CI42090)

Questions?

Call toll-free 800-323-2220

Manufactured for Sage Products LLC Cary, IL

Oral Cleansing & Suctioning System

q4°

Setup Instructions: Multi-Port Canister

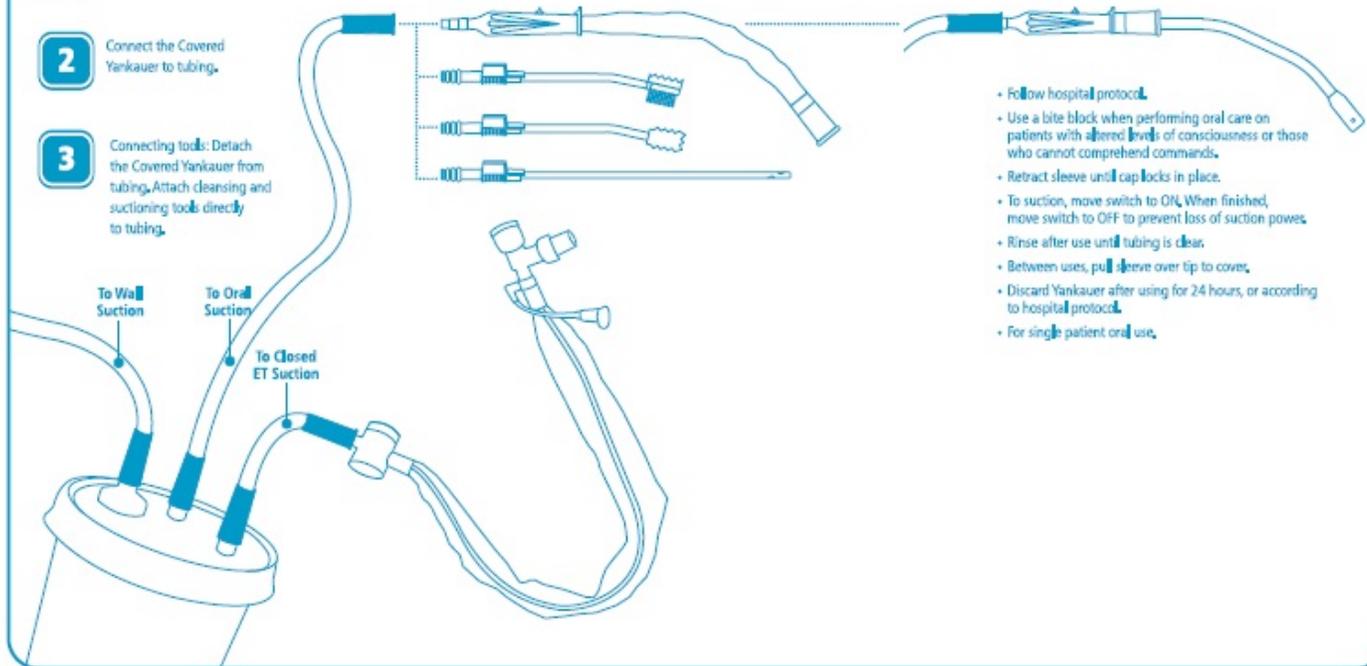
1 Connect tubing to suction part on canister.

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 protocols.
- 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.

Contents:

- 1 Covered Yankauer
- 2 Untreated Suction Toothbrush packages with Antiplaque solution
- 4 Suction Oral Swab packages with Perox-A-Mint® solution
- 2 Oropharyngeal Suction Catheter packages

Ingredients:

Antiplaque solution active ingredient: Cetylpyridinium chloride .05%
Perox-A-Mint® solution active ingredient: Hydrogen peroxide 1.5%
Kit also contains sodium bicarbonate and Mouth Moisturizer. 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 # 6504



SAGE
PRODUCTS

SAGE PRODUCTS LLC
3909 Three Oaks Road
Cary, Illinois 60013
www.sageproducts.com
800-323-2220

Contents:

- 1 Covered Yankauer
- 2 Untreated Suction Toothbrush packages with Antiplaque solution
- 4 Suction Oral Swab packages with Perox-A-Mint® solution
- 2 Oropharyngeal Suction Catheter packages

Ingredients:

Antiplaque solution active ingredient: Cetylpyridinium chloride .05%

Perox-A-Mint® solution active ingredient: Hydrogen peroxide 1.5%

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R6037

Q-Care® Oral Cleansing and Suctioning System, q4°

Suction Swab with Perox-A-Mint® Solution

CONTENTS: 1 Suction Swab with sodium bicarbonate 25 g, 0.2/7ml Perox-A-Mint Solution, 0.07 0.2/2g Mouth Moisturizer, 1 Applicator Swab

Drug Facts	
Active ingredient	Purpose
PEROX-A-MINT® Hydrogen peroxide 1.5%.....	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 suction 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.	
Inactive ingredients*	
Water, menthol flavor, polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI 42090), Yellow 6 (CI 15985).	
Questions? Call toll-free 800-323-2220.	

Sodium Bicarbonate Ingredients*: Water, sodium bicarbonate, sodium carboxymethyl cellulose, sodium lauryl sulfate, flavor, sodium saccharin, sodium benzoate.

Mouth Moisturizer Ingredients*: Water, coconut oil, ylang ylang, spearmint flavor, sodium carboxymethyl cellulose, triphenyl acetate (vitamin E), spearmint oil, carbomer, polysorbate 20, polysorbate 80, potassium sorbate, cetylpyridinium chloride.

* Manufactured for Sage Products LLC • Cary, IL
Covered under one or more of the following patents: 5,085,633; 5,151,094; 5,378,226

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



3 53462-075-60 5

Suction Swab with Perox-A-Mint® Solution

CONTENTS: 1 Suction Swab with sodium bicarbonate 25 g, 0.2/7ml Perox-A-Mint Solution, 0.07 0.2/2g Mouth Moisturizer, 1 Applicator Swab

Drug Facts	
Active ingredient	Purpose
PEROX-A-MINT® Hydrogen peroxide 1.5%.....	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 suction 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.	
Inactive ingredients*	
Water, menthol flavor, polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI 42090), Yellow 6 (CI 15985).	
Questions? Call toll-free 800-323-2220.	

Sodium Bicarbonate Ingredients*: Water, sodium bicarbonate, sodium carboxymethyl cellulose, sodium lauryl sulfate, flavor, sodium saccharin, sodium benzoate.

Mouth Moisturizer Ingredients*: Water, coconut oil, ylang ylang, spearmint flavor, sodium carboxymethyl cellulose, triphenyl acetate (vitamin E), spearmint oil, carbomer, polysorbate 20, polysorbate 80, potassium sorbate, cetylpyridinium chloride.

* Manufactured for Sage Products LLC • Cary, IL
Covered under one or more of the following patents: 5,085,633; 5,151,094; 5,378,226

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3 53462-075-60 5

Suction Toothbrush with Antiplaque Solution

CONTENTS: 1 Untreated Suction Toothbrush with 25 g, 0.2/7ml Antiplaque Solution, 0.07 0.2/2g Mouth Moisturizer, 1 Applicator Swab

Drug Facts	
Active ingredient	Purpose
ANTIPLAQUE® Cetylpyridinium chloride 0.05%.....	Antigingivitis/antiplaque
Uses	
• Aids in the removal and prevention of plaque that leads to gingivitis.	
Warnings	
Stop use and ask a dentist if:	
• Gingivitis, bleeding or redness persists for more than 2 weeks.	
• You have painful or swollen gums, pus from the gum line, loose teeth or increasing spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.	
Keep out of reach of children under 6 years of age.	
If more than used for brushing 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.	
• Remove Mouth Moisturizer and Applicator Swab.	
• 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.	
• Place Mouth Moisturizer on Applicator Swab.	
• Apply as needed to lips and inside mouth.	
• Adults and children 12 years of age and older: use two times daily or as directed by a dentist. Do not swallow the solution.	
• Children ages 6 to 12 years: supervise use.	
• Children under 6 years of age: do not 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.	
Inactive Ingredients*	
Water, sorbitol, peppermint flavor, potassium sorbate, polysorbate 80, polysorbate 20, citric acid, Blue 1 (CI 42090).	
Questions? Call toll-free 800-323-2220.	

Mouth Moisturizer Ingredients*: Water, coconut oil, ylang ylang, spearmint flavor, sodium carboxymethyl cellulose, triphenyl acetate (vitamin E), spearmint oil, carbomer, polysorbate 20, polysorbate 80, potassium sorbate, cetylpyridinium chloride.

* Manufactured for Sage Products LLC • Cary, IL
U.S. Patent No. 6,338,213

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Oropharyngeal Suction Catheter Non-sterile

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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QCARE ORAL CLEANSING AND SUCTIONING SYSTEM, Q4

cetylpyridinium chloride and hydrogen peroxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53462-504
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-504-60	1 in 1 KIT		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 POUCH	7 mL
Part 2	1 POUCH	7 mL

Part 1 of 2

TOOTHETE 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: 059QF0KO0R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 PACKAGE		
1		2 in 1 PACKET		
1		7 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 2 of 2

SUCTION TOOTHBRUSH WITH ANTIPLAQUE SOLUTION

cetylpyridinium chloride mouthwash

Product Information

Route of Administration BUCCAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPIRIDINIUM - UNII:CUB7J10JV3)	CETYLPIRIDINIUM CHLORIDE	.5 [iU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
PEPPERMINT (UNII: V95R5KMY2B)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 PACKAGE		
1		2 in 1 PACKET		
1		7 mL in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part356	05/21/1998	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part356	05/21/1998	

Labeler - Sage Products LLC (054326178)

Registrant - Sage Products LLC (054326178)

Establishment

Name	Address	ID/FEI	Business Operations
ChemRite CoPac, Inc.		623776502	MANUFACTURE(53462-504)

Establishment

Name	Address	ID/FEI	Business Operations
Sage Products LLC		054326178	MANUFACTURE(53462-504)

Revised: 8/2013

Sage Products LLC