QCARE- 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.

Corinz[™] Antiseptic Cleansing and Moisturizing Oral Rinse

Drug Facts

Active ingredient:PurposeCORINZ ANTISEPTIC CLEANSING AND MOISTURIZING ORAL
RINSE:PurposeCetylpyridinium 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

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.

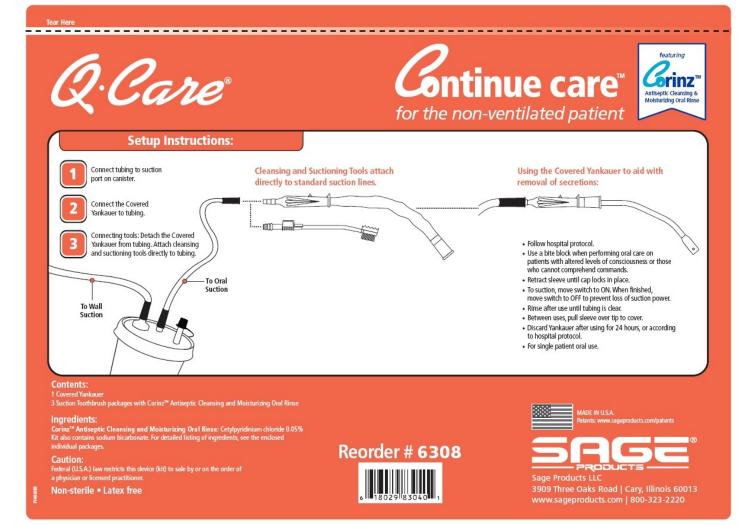
Inactive ingredients

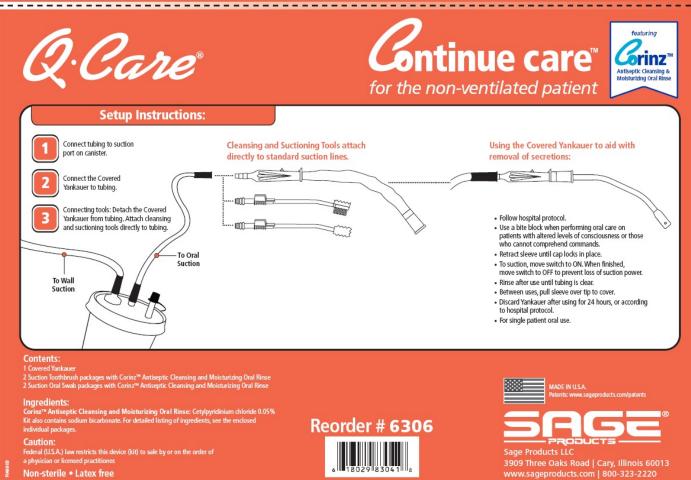
Water, glycerin, xylitol, spearmint flavor, potassium sorbate, polysorbate 20, polysorbate 80, hydroxyethylcellulose, citric acid, sodium saccharin, menthol.

Questions?

Call toll-free 800-323-2220.

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





Non-sterile • Latex free

Tear H



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

Drug Facts

Purpose

Active ingredient 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

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Directions

- 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.

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.



and 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.
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Directions

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- Peel lid to open.
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- · Clean teeth and oral cavity for approximately one minute.
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- Use up to 4 times daily or as directed by a dentist or doctor.
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- 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 carboxymethyl cellulose, sodium lauryl sulfate, flavor, sodium saccharin, sodium benzoate.

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

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Oral Check Scan bar code for compliance to protocol



TΜ **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

LOT

R5439

| Product Inform | ation | | | | | |
|---|---|----------------------|--------------------------|-----------------------------|-----------------------|--|
| Product Type | HUMAN O | TC DRUG | Item Code (Source) | NDC:53 | 462-306 | |
| | | | | | | |
| Packaging | | | | | | |
| # Item Code | | Package Descrip | otion | Marketing Start Date | Marketing End Date | |
| | 1 in 1 KIT; Type 4: 1 with Drug | Device Coated/Impreg | nated/Otherwise Combined | | | |
| | | | | | | |
| Quantity of Part | S | | | | | |
| Part # | Package Quantity Total Product Quantity | | | | | |
| Part 1 4 POUCH | | | 28 mL | | | |
| | | | | | | |
| Part 1 of 1 | | | | | | |
| CORINZ | | | | | | |
| cetylpyridinium ch | lorido rinco | | | | | |
| | | | | | | |
| | | | | | | |
| Product Inform | ation | | | | | |
| Item Code (Source | ce) NDC:53462-375 | | | | | |
| Route of Administr | oute of Administration ORAL | | | | | |
| | | | | | | |
| Active Ingredie | nt/Active Moie | ety | | | | |
| Ingredient Name Basis of Strength | | | | | | |
| CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CE UNII:CUB7JI0JV3) | | | YLPYRIDINIUM - | CETYLPYRIDINIUM CHLORIDE | .5 mg in 1 mL | |
| | | | | | | |
| Inactive Ingredi | ients | | | | | |
| Ingredient Name | | | | | | |
| WATER (UNII: 059Q) | | | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | | | |
| XYLITOL (UNII: VCQ006KQ1E) | | | | | | |
| POTASSIUM SORBA | | | | | | |
| POLYSORBATE 20 | | | | | | |
| POLYSORBATE 80 | | | | | | |
| | | 0 MPA.S AT 1%) (UN | III: ZYD53NBL45) | | | |
| CITRIC ACID MONO | | | | | | |
| SACCHARIN SODIU | | | | | | |
| MENTHOL, UNSPEC | CIFIED FORM (UN | II: L7T10EIP3A) | | | | |
| | | | | | | |
| | | | | | | |

| Packaging | | | | | | | |
|----------------------------------|--|----------------------|--------------------------|-----------------------------|-------------|-------------------------|--|
| # Item Code | Package I | Description | Marketing St | art Date | Marke | eting End Date | |
| 1 Item Coue | 1 in 1 PACKET | | | Start Date Mai | | rketing End Date | |
| 1 | 7 mL in 1 POUCH | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Marketing Inf | formation | | | | | | |
| Marketing Catego | Marketing Category Application Number or M | | nograph Citation Marketi | | art Date N | Aarketing End Date | |
| DTC monograph not final part356 | | | 1 | | | | |
| | | | | | | | |
| | | | | | | | |
| Marketing Information | | | | | | | |
| Marketing Catego | ory Applicati | on Number or Mor | nograph Citation | Marketing St | art Date M | Date Marketing End Date | |
| OTC monograph not f | inal part356 | | | 12/28/2001 | | | |
| | | | | | | | |
| | | | | | | | |
| QCARE | | | | | | | |
| cetylpyridinium chlo | oride kit | | | | | | |
| | | | | | | | |
| Product Informa | ition | | | | | | |
| Product Type | HUMAN O | TC DRUG | Item Code (So | urce) | NDC: | 53462-308 | |
| | | | | | | | |
| | | | | | | | |
| Packaging | | | | | · · · · · | Marketing End | |
| # Item Code | | Package Descrij | ption | Marketing Start Mar Date | | | |
| 1 NDC:53462-308- 1 | in 1 KIT; Type 4: I | Device Coated/Impreg | gnated/Otherwise Com | ıbined | | | |
| 6 0 v | vith Drug | | | | | | |
| | | | | | | | |
| Quantity of Parts | 6 | | | | | | |
| Part # | S Package Qua | ntity | | Total Produ | uct Quantit | *7 | |
| Part 1 3 POUCH | Tackage Qua | Intity | 21 mL | | uci Quantii | · y | |
| | | | | | | | |
| | | | | | | | |
| Part 1 of 1 | | | | | | | |
| | | | | | | | |
| CORINZ | | | | | | | |
| cetylpyridinium chl | oride rinse | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Product Informa | ntion | | | | | | |
| Item Code (Source) NDC:53462-375 | | | | | | | |
| Route of Administration ORAL | | | | | | | |
| Route of Administr | ation | ORAL | | | | | |
| Route of Administr | ation | ORAL | | | | | |

| Active Ingre | alent/A | | | | | | |
|--|---|---|-------------------|--------------------------|---------------------|------------------|--|
| | | Ingredient Name | | Basis of Streng | | Strengt | |
| CETYLPYRIDIN UNII:CUB7J10JV | | ORIDE (UNII: D9OM4SK49P) (CI | ETYLPYRIDINIUM - | CETY CHLO | LPYRIDINIUM RIDE | .5 mg in 1 mL | |
| Inactive Ing | redients | | • NT | | | | |
| WATER (UNII: 0 | 59 O FO KO | Ingredien | t Name | | | Strength | |
| GLYCERIN (UN | | | | | | | |
| XYLITOL (UNII | | | | | | | |
| | | UNII: 1VPU26JZZ4) | | | | | |
| POLYSORBAT | | | | | | | |
| POLYSORBATE 80 (UNII: 60ZP39ZG8H) | | | | | | | |
| | | JLOSE (4000 MPA.S AT 1%) (U | INII: ZYD53NBL45) | | | | |
| CITRIC ACID M | O NO HYD | RATE (UNII: 2968PHW8QP) | | | | | |
| ciriae neib m | | | | | | | |
| | DIUM (UN | NII: SB8ZUX40TY) | | | | | |
| SACCHARIN SC | | NII: SB8ZUX40TY) DFORM (UNII: L7T10EIP3A) | | | | | |
| SACCHARIN SC MENTHOL, UN | | | | | | | |
| saccharin sc menthol, uns Packaging | SPECIFIEI | DFORM (UNII: L7T10EIP3A) | Marketing St | tart Date | Marketing | Fnd Date | |
| SACCHARIN SC MENTHOL, UN Packaging # Item Coc | SPECIFIEI | PFORM (UNII: L7T10EIP3A) Package Description | Marketing St | tart Date | Marketing | End Date | |
| SACCHARIN SC MENTHOL, UN Packaging # Item Coc 1 | SPECIFIEI le 1 in | PFORM (UNII: L7T10EIP3A) Package Description 1 PACKET | Marketing St | tart Date | Marketing | End Date | |
| SACCHARIN SC MENTHOL, UN Packaging | SPECIFIEI le 1 in | PFORM (UNII: L7T10EIP3A) Package Description | Marketing St | tart Date | Marketing | End Date | |
| SACCHARIN SC MENTHOL, UNS Packaging # Item Coc 1 1 | SPECIFIEI le 1 in 7 ml | PACKAGE Description 1 PACKET L in 1 POUCH | Marketing St | tart Date | Marketing | End Date | |
| SACCHARIN SC MENTHOL, UNS Packaging # Item Coc 1 1 | SPECIFIEI le 1 in 7 ml | PACKAGE Description 1 PACKET L in 1 POUCH | Marketing St | tart Date | Marketing | End Date | |
| SACCHARIN SC MENTHOL, UNS Packaging # Item Coc 1 1 | SPECIFIEI | PACKAGE Description 1 PACKET L in 1 POUCH | | tart Date Marketing S | | End Date | |
| SACCHARIN SC MENTHOL, UN Packaging # Item Coc 1 1 Marketing Co | SPECIFIEI 1 in 7 ml 1 in 1 ategory | PACKAGE Description PACKET in 1 POUCH mation | | | | | |
| SACCHARIN SC MENTHOL, UNS Packaging # Item Coc 1 1 1 Marketing C | SPECIFIEI 1 in 7 ml 1 in 1 ategory | Package Description PackET in 1 POUCH Application Number or Mo | | Marketing S | | | |
| SACCHARIN SC MENTHOL, UNS Packaging # Item Coc 1 1 1 Marketing Cor OTC monograph | SPECIFIEI Ie 1 in 7 m 5 Infor ategory not final | Package Description PACKET in 1 POUCH Application Number or Mo part356 | | Marketing S | | | |
| SACCHARIN SC MENTHOL, UNS Packaging # Item Coc 1 1 1 Marketing | SPECIFIEI | Package Description PACKET in 1 POUCH Application Number or Mo part356 | nograph Citation | Marketing S | tart Date Marke | | |

Labeler - Sage Products LLC (054326178)

Registrant - Sage Products LLC (054326178)

| Establishment | | | | | | |
|-------------------|---------|-----------|-----------------------------------|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | |
| Sage Products LLC | | 054326178 | MANUFACTURE(53462-308, 53462-306) | | | |