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.
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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.

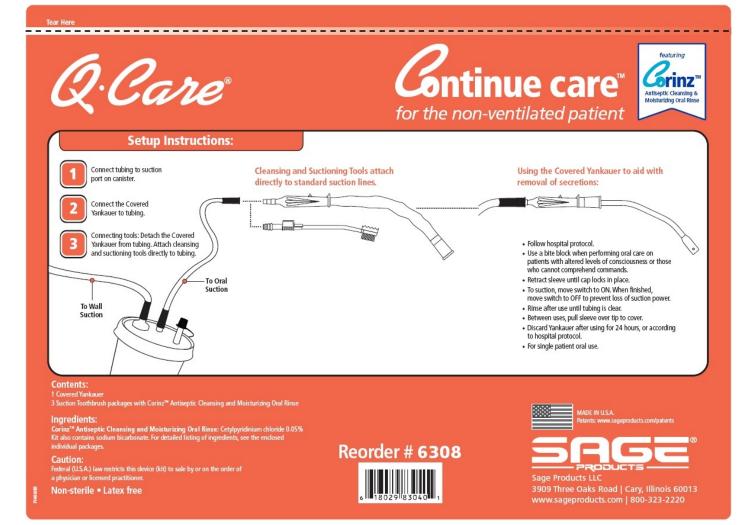
Inactive ingredients

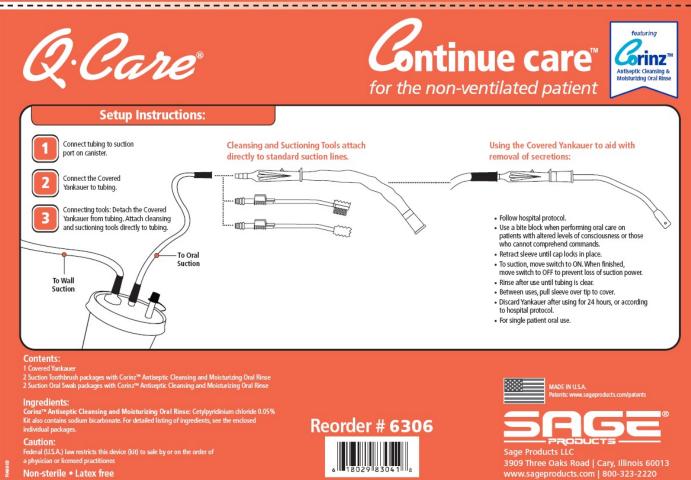
Water, glycerin, xylitol, spearmint flavor, potassium sorbate, polysorbate 20, polysorbate 80, hydroxyethylcellulose, citric acid, sodium saccharin, menthol.

Questions?

Call toll-free 800-323-2220.

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.

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- · 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:

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Directions

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- 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)			