SUCTION TOOTHBRUSH WITH CORINZ 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.

Suction Toothbrush with Corinz® Oral Rinse

Use

Helps reduce chance of infection in minor oral irritation.

Drug Facts

Active Ingredient:PurposeCetylpyridinium chloride 0.05%Antiseptic Rinse

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

- Use up to 4 time daily or as directed by a dentist or doctor.
- Adults and children 3 years and older: rinse mouth with 1/2 Tbsp. for approx. one minute. Instruct to expectorate.
- Children under 3 years of age: consult a doctor.

Inactive Ingredients

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

Questions?

Call toll-free 800-323-2220 NOT MADE WITH NATURAL RUBBER LATEX MADE IN USA



Toothbrush

For healthcare professional use

CONTENTS: (1) Suction Toothbrush



with sodium bicarbonate, (1) Applicator Swab with sodium bicarbonate, 0.25 fl. oz./7 ml Corinz Antiseptic Cleansing and Moisturizing Oral Rinse

Drug Facts

Active ingredient

Purpose

Cetylpyridinium chloride 0.05%...Antiseptic Rinse

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Directions

- Use up to 4 times daily or as directed by a dentist or doctor.
- Adults and children 3 years and older: rinse mouth with 1/2 Tbsp. for approximately 1 minute. Instruct to expectorate.
- Children under 3 years of age: consult a dentist or doctor.
- Children under 12 years of age: supervise use.

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

INSTRUCTIONS FOR USE

- Before opening, turn package over, burst solution packet with thumbs.
- Peel lid to open.
- Attach Suction Toothbrush to suction line.
- Clean teeth and oral cavity for 1 minute.
- To suction, place thumb over port.
- Clear tubing after use.
- Repeat cleaning with other swab as needed.
- Discard tools after use.
- . Hen a hite block if nationt has altered levels

- Ose a bite block if patient has aftered levels of consciousness or cannot comprehend commands.
- Ensure foam is intact after use. If not, remove particles from oral cavity.

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

*Manufactured for Sage Products LLC

NOT MADE WITH NATURAL RUBBER LATEX
SINGLE USE ONLY • MADE IN U.S.A.

Reorder #6561

Sage Products LLC

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Patents: www.sageproducts.com/patents





Active Ingredient: Cetylpyridinium chloride 0.05%



BURST PACKET BEFORE OPENING OUTER PACKAGE

> Do not remove from package 0.25 fl. oz./7 mL

R5439



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SUCTION TOOTHBRUSH WITH CORINZ ORAL RINSE

cetylpyridinium chloride kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:53462-561

I	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:53462-561-60	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	0 1/24/20 18		

Quan	Quantity of Parts			
Part #	Package Quantity	Total Product Quantity		
Part 1	1 PACKET	7 mL		
Part 2		1		

Part 1 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 CHLO RIDE (UNII: D9 O M4SK49 P) (CETYLPYRIDINIUM - UNII: CUB7JI0 JV3)	CETYLPYRIDINIUM CHLORIDE	0.5 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
XYLITOL (UNII: VCQ006KQ1E)			
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
POLYSORBATE 20 (UNII: 7T1F30V5YH)			
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)			
HYDROXYETHYL CELLULOSE (4000 MPA.S AT 1%) (UNII: ZYD53NBL45)			
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)			
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 KIT		
1	NDC:53462-375-60	7 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC monograph not finalpart35606/21/2000

Part 2 of 2

SODIUM BICARBONATE

other oral hygiene products

Product Information

Other Ingredients			
Ingredient Kind Ingredient Name		Quantity	
INGR	SODIUM BICARBONATE (UNII: 8 MDF5 V39 QO)		
INGR	CARBO XYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)		
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			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	0 1/24/20 18	

Labeler - Sage Products, LLC (054326178)

Registrant - Sage Products, LLC (054326178)

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