CVS ANTISEPTIC- cetylpyridinium chloride rinse CVS Pharmacy, Inc

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.

CVS 299.005/299AK-AL Anitseptic Mouthrinse

Active ingredient

Cetylpyridinium chloride 0.07%

Purpose

Antigingivitis, Antiplaque

Use

helps control plaque that leads to gingivitis

warnings

for this product

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 gun line, loose teeth or increased 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 rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 6 years + older: rinse for 30 seconds with 20 mL (4 teaspoonfuls) twice a day
- do not swallow
- children two years to under 12 years of age: supervise use
- when used after brushng, rinse mouth with water first
- children under 6 years of age: do not use

Other information

• this rinse is not intended to replace brushing or flossing

Inactive ingredients

water, glycerin, flavor, poloxamer 188, sodium saccharin, propylene glycol, sodium benzoate, benzoic acid, blue 1

*This product is not manufactured or distributed by Procter + Gamble, distributor of Crest Pro-Health Multi-Protection Alcohol Free Rinse - Refreshing Clean Mint

This rinse may cause temporary staining to the sufrace of teeth. This is not harmful and adequate brushing may prevent its occurrence.

Distributed by: CVS Pharmacy, Inc.

Once CVS Drive, Woonsocket, RI 02895

CVS.com 1-800-SHOP CVS

principal display panel

ALCOHOL FREE

CVS Health

Compare to the active ingredient in Crest Pro-Health Rinse*

ANTISEPTIC ORAL RINSE

Sealed with printed neckband for your protection

ANTIGINGIVITIS/ANTIPLAQUES

Kills germsHelps keep teeth feeling cleanFreshens breath No burn of alcohol 3 FL OZ (89 mL)



cetylpyridinium chloride rinse

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-299
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII: CUB7JI0JV3)	CETYLPYRIDINIUM CHLORIDE	0.7 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLOXAMER 188 (UNII: LQA7B6G8JG)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
BENZOIC ACID (UNII: 85KN0B0MIM)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			

F	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779- 299-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2007	
2	NDC:59779- 299-21	89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2007	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/01/2007	

Labeler - CVS Pharmacy, Inc (062312574)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(59779-299)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(59779-299)

Revised: 9/2023 CVS Pharmacy, Inc