KIMVENT ORAL CARE TOOTHBRUSH PACK- cetylpyridinium chloride Halyard Health

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.

KimVent* Toothbrush Pack with Antiplaque Solution

Drug Facts

Active Ingredient

Cetylpyridinium Chloride 0.05

Purpose

Antigingivitis/Antiplaque

Uses

• Helps remove plaque that leads to gingivitis.

Warnings

Stop use and ask a doctor 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 or 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 12 years of age and older: Use as directed by a dentist. Do not swallow the rinse
- Children 6 years to under 12 years of age: supervised use.
- Children under 6 years of age: do not use.
- Use only under health care practitioner's supervision.

Other Information

- This rinse is not intended to replace brushing or flossing.
- Store at room temperature.

Inactive Ingredients

Purified Water, Glycerin, Sorbitol, Flavor, Benzoic Acid, Sodium Benzoate, Sodium Saccharin, D&C Green 5

Questions or Comments?

1-800-KCHELPS

Distributed in the U.S. by Kimberly-Clark Global Sales, LLC, Roswell, GA 30076 USA

PRINCIPAL DISPLAY PANEL - Kit Carton

Peel Here

Kimberly-Clark*

KimVent*
Toothbrush
Pack with Antiplaque
Solution

Contains:

- 1 Suction Toothbrush
- 1 Applicator Swab
- 0.5 fl. oz. (14mL) of 0.05% Antiplaque Solution
- 0.07 oz. (2g) Mouth Moisturizer Purified Water, Propylene Glycol Sorbitol, Hydroxypropyl Methylcellulose, Dimethicone, Flavor, Xylitol, Aloe Vera Gel, Potassium Sorbate, Sodium Benzoate, Potassium Chloride, Sodium Chloride





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Antiplaque Solution

DRUG FACTS

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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 12 years of age and older: Use as directed by a dentist. Do not swallow the rinse.
- . Children 8 years to under 12 years of age; supervised use.
- . Children under 6 years of age: do not use.
- · Use only under health care practitioner's supervision.

Other Information

- This rinse is not intended to replace brushing or flossing.
- · Store at room temperature.

Inactive Ingredients

Purified Water, Glycerin, Sorbitol, Flavor, Benzoic Acid, Sodium Benzoate, Sodium Saccharin, D&C Green 5

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Latex-Free



REF 99791

For use with KawVent* 24-Hour Oral Care Kit

Distributed in the U.S. by Kimberly-Clark Global Sales, LLC, Roswell, GA 20076 USA Comments? Questions? Please cell 1-800-KCHELPS; www.kchealthcare.com

Made in China

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KIMVENT ORAL CARE TOOTHBRUSH PACK

cetylpyridinium chloride kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69697-980

Packaging

П				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:69697-980-01	1 in 1 CARTON		

Quantity of Parts

Quan	Quality of Faits			
Part #	Package Quantity	Total Product Quantity		
Part 1	1 CUP, UNIT-DOSE	14 mL		
Part 2	1 TUBE	10 g		

Part 1 of 2

CETYLPYRIDINIUM CHLORIDE

cetylpyridinium chloride mouthwash

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

Cetylpyridinium Chloride (UNII: D9OM4SK49P) (Cetylpyridinium - UNII:CUB7JI0JV3) Cetylpyridinium Chloride 0.0005 mg in 1 mL

T	. •	т .	1.
ına	ctive	Ingre	dients

Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
Benzoic Acid (UNII: 8 SKN0 B0 MIM)		
Saccharin Sodium (UNII: SB8ZUX40TY)		
Sodium Benzoate (UNII: OJ245FE5EU)		
Glycerin (UNII: PDC6A3C0OX)		

D&C Green No. 5 (UNII: 8J6RDU8L9X)	
Sorbitol (UNII: 506T60A25R)	
Mint (UNII: FV98Z8GITP)	

Product Characteristics			
Color	BLUE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		14 mL in 1 CUP, UNIT-DOSE; Type 1: Convenience Kit of Co-Package		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	03/13/2008	

Part 2 of 2

MOUTH MOISTURIZER

other oral hygiene products salve

Product Information

Route of Administration ORAL

Other Ingredients		
Ingredient Kind	Ingredient Name	Quantity
INGR	Water (UNII: 059QF0KO0R)	
INGR	Xylitol (UNII: VCQ006KQ1E)	
INGR	Sodium Benzoate (UNII: OJ245FE5EU)	
INGR	Aloe Vera Flower (UNII: 575DY8C1ER)	
INGR	Propylene Glycol (UNII: 6DC9Q167V3)	
INGR	Potassium Sorbate (UNII: 1VPU26JZZ4)	
INGR	Sorbitol (UNII: 506T60A25R)	
INGR	Hydroxypropyl Cellulose (Type H) (UNII: RFW2ET671P)	
INGR	Dimethicone (UNII: 92RU3N3Y1O)	
INGR	Potassium Chloride (UNII: 660 YQ 98 I10)	

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	10 g in 1 TUBE; Type 1: Convenience Kit of Co-Packag	ge			
Marketing Information					
Marketing Cat	egory Application Number or Monograph Ci	tation Marketing Start Date	Marketing End Date		
Cosmetic		03/13/2008			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/13/2008	

Labeler - Halyard Health (079617666)

Establishment			
Name	Address	ID/FEI	Business Operations
Avent		049316284	MANUFACTURE(69697-980), RELABEL(69697-980), REPACK(69697-980)

Establishment			
Name	Address	ID/FEI	Business Operations
Elba		108428483	MANUFACTURE(69697-980)

Revised: 3/2015 Halyard Health