

KALAYA BREATH REFRESH- mouthwash liquid

Avaria Health and Beauty Corp

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.

Kalaya Breath Refresh Antiseptic Oral Rinse-updated label for NDC

Active Ingredients

Cetylpyridinium Chloride (0.07%)

Keep out of reach of children under 6 years old

- If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away

Purpose

Antigingivitis/Antiplaque

Inactive Ingredients

Water, Glycerin, Xylitol, Hydroxypropyl Methylcellulose, Polaxmer 407, Mentha Piperita (Peppermint) Leaf Oil, Mentha Spicata (Spearmint) Leaf Oil, Natural Flavour

A Synergistic Blend of Science & Nature

Warnings

Stop use and ask a dentist if

- Gingivitis, bleeding, or redness persists for more than 2 weeks
- You have painful or swollen gums, puss from the gum line, loose teeth or increased spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease

Uses

Helps control plaque that leads to gingivitis

Directions

- Adults and children 12 years of age and older: vigorously swish 20 mL (4 teaspoonfuls) of rinse between your teeth twice a day for 30 seconds and then spit out
- Do not swallow the rinse
- Children 6 years to under 12 years of age: supervise use
- When used after brushing, rinse mouth with water first
- Children under 6 years of age: do not use

NDC 43493-0005-1



ANTISEPTIC ORAL RINSE

BREATH REFRESH

FOLD LINE

- 1 freshens breath
- 2 prevents gingivitis
- 3 alcohol free, burn free
- 4 long lasting
- 5 reduces plaque
- 6 great taste

with easypour measured dispenser

16.9 fl oz
(500 mL)

KALAYA BREATH REFRESH

mouthwash liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43493-0005
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7J10JV3)		CETYLPYRIDINIUM CHLORIDE	0.7 mg in 1 mL	
Inactive Ingredients				
Ingredient Name		Strength		
XYLITOL (UNII: VCQ006KQ1E)				
GLYCERIN (UNII: PDC6A3C0OX)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
WATER (UNII: 059QF0KO0R)				
POLOXAMER 407 (UNII: TUF21VW3M2)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
SPEARMINT OIL (UNII: C3M81465G5)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	PEPPERMINT, SPEARMINT	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43493-0005-1	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	11/16/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	11/16/2018		

Labeler - Avaria Health and Beauty Corp (251366043)

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