

COLGATE ENAMEL HEALTH MOUTHWASH- sodium fluoride rinse
Colgate-Palmolive Company

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.

Colgate® Enamel Health™ Mouthwash

Drug Facts

Active ingredient

Sodium fluoride 0.02% (0.01% w/v fluoride ion)

Purpose

Anticavity

Uses

aids in the prevention of dental cavities

Warnings

Keep out of reach of children. 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 of age and older:

- use twice a day after brushing your teeth with a toothpaste
- vigorously swish 10 mL (2 teaspoonfuls) of rinse between your teeth for 1 minute and then spit out
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
- instruct children under 12 years of age in good rinsing habits (to minimize swallowing)
- supervise children as necessary until capable of using without supervision

Children under 6 years of age: consult a dentist or doctor

Inactive ingredients

water, glycerin, propylene glycol, sorbitol, poloxamer 338, poloxamer 407, flavor, PEG-40 castor oil, phosphoric acid, sodium saccharin, cetylpyridinium chloride, disodium phosphate, potassium sorbate, sucralose, FD&C green no. 3

Other Information

Store at controlled room temperature 68 – 77° F (20 – 25°C)

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

PRINCIPAL DISPLAY PANEL - 1 L Bottle Label

NEW

ALCOHOL FREE

Colgate®

Anticavity Fluoride Mouthwash

ENAMEL

HEALTH™

STRENGTHENS ENAMEL EVEN

WHERE BRUSHING MAY MISS

WITH FLUORIDE

- ▣ **HELPS REPLENISH NATURAL CALCIUM
BACK INTO ENAMEL**
- ▣ **REVERSES ENAMEL SOFTENING TO HELP
PREVENT CAVITIES**
- ▣ **FRESHENS BREATH**

SPARKLING FRESH MINT

33.8 FL OZ

(1.05 QT)

1 L

IMPORTANT:

Read directions

for proper use

P9903598

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ENAMEL HEALTH™

- Strengthens enamel even where brushing may miss
- To promote healthy teeth and stronger enamel use after brushing with Colgate® Enamel Health™ toothpaste and toothbrush



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Drug Facts (continued)

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COLGATE ENAMEL HEALTH MOUTHWASH

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-728
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLOXAMER 338 (UNII: F75JV2T505)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-728-16	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2015	
2	NDC:35000-728-33	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2015	
3	NDC:35000-728-84	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	08/01/2015	

Labeler - Colgate-Palmolive Company (001344381)**Establishment**

Name	Address	ID/FEI	Business Operations
Colgate-Palmolive		785047999	MANUFACTURE(35000-728)

Revised: 12/2019

Colgate-Palmolive Company