

COLGATE HYDRIS DRY MOUTH- sodium fluoride gel, dentifrice

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® Hydris™ Dry Mouth

Drug Facts

Active ingredient

Sodium fluoride 0.24%
(0.15% w/v fluoride ion)

Purpose

Anticavity

Use

helps protect against cavities

Warnings

Keep out of reach of children under 6 years of age.

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

Directions

adults and children 2 years of age and older	brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician
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children 2 to 6 years	use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)
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children under 2 years	ask a dentist or physician
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Inactive ingredients

sorbitol, water, hydrated silica, PEG-12, hydrogenated coconut oil, sodium lauryl sulfate, flavor, cellulose gum, sodium saccharin, tetrasodium pyrophosphate, cocamidopropyl betaine, FD&C blue no. 1

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY
New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 119 g Tube Carton

NEW

Colgate®

Anticavity Fluoride Toothpaste

- Soothes mouth dryness
- Helps prevent cavities
- Freshens breath

Hydris™

DRY MOUTH

LOCKS IN A HYDRATED FEELING

4 HOURS OF LASTING COMFORT

NET WT 4.2 OZ (119 g)

#1

COLGATE:

DENTIST RECOMMENDED

ORAL CARE BRAND

HYDRAMINT™

gel



COLGATE HYDRIS DRY MOUTH

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-210
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.4 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDROGENATED COCONUT OIL (UNII: JY81OXM1OM)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	GREEN (Light green)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-210-71	1 in 1 CARTON	12/01/2017	01/01/2022
1		119 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	12/01/2017	

Labeler - Colgate-Palmolive Company (001344381)

Establishment

Name	Address	ID/FEI	Business Operations
Colgate-Palmolive		785047999	MANUFACTURE(35000-210)

Revised: 12/2019

Colgate-Palmolive Company