

COLGATE JUNIOR FRESH PROTECT- sodium fluoride paste, dentifrice
Mission Hills, S.A.de C.V.

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®
Junior Fresh Protect™

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 |
| children 2 to 6 years | use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing) |
| children under 2 years | ask a dentist or physician |

Inactive ingredients

sorbitol, water, hydrated silica, PEG-12, cellulose gum, sodium lauryl sulfate, flavor, sodium saccharin, mica, titanium dioxide, FD&C blue no. 1

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

PRINCIPAL DISPLAY PANEL - 24 g Tube Carton

Colgate®
Anticavity Fluoride Toothpaste

FRESH
'N PROTECT™

CLINICALLY PROVEN CAVITY AND ENAMEL PROTECTION

mild mint flavor toothpaste

ages 8 +

FRESH 'N PROTECT

ADA
Accepted
American
Dental
Association®

NET WT 0.85 OZ (24 g)



COLGATE JUNIOR FRESH PROTECT

sodium fluoride paste, dentifrice

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:65954-556 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | SODIUM FLUORIDE | 0.24 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|---------------|
| SORBITOL (UNII: 506T60A25R) | 476 mg in 1 g |
| WATER (UNII: 059QF0KO0R) | |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | |
| POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9) | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY) | |
| MICA (UNII: V8A1AW0880) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |

Product Characteristics

| | | | |
|----------|-------|--------------|--|
| Color | BLUE | Score | |
| Shape | | Size | |
| Flavor | FRUIT | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:65954-556-20 | 1 in 1 CARTON | | |
| 1 | | 24 g in 1 TUBE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part355 | 12/01/2011 | |

