

COLGATE JUNIOR TRANSFORMERS- 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 Transformers™ Fluoride Toothpaste

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, flavor, sodium lauryl sulfate, 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 - 130 g Tube Label

Colgate®

Fluoride Toothpaste

CLINICALLY PROVEN

Cavity & Enamel Protection

ADA

Accepted

American

Dental

Association®

Toothpaste

TRANS

FORMERS™

NET WT

4.6 OZ

(130 g)

MILD BUBBLE FRUIT® FLAVOR

Colgate®

Fluoride Toothpaste

CLINICALLY PROVEN
Cavity & Enamel Protection



Toothpaste

TRANSFORMERS™

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TWIST OFF CAP AND REMOVE FOIL SEAL. DO NOT USE IF SEAL IS NOT INTACT.

"The ADA Council on Scientific Affairs' Acceptance of Colgate for Kids toothpaste is based on its finding that the product is effective in helping to prevent and reduce tooth decay, when used as directed."

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Dist. by:
COLGATE-PALMOLIVE COMPANY

New York, NY 10022 Made in Mexico
www.colgate.com

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COLGATE JUNIOR TRANSFORMERS

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65954-547
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:65954-547-46	130 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	

Labeler - Mission Hills, S.A. de C.V. (812312122)

