

COLGATE TRIPLE ACCION- sodium fluoride paste, dentifrice
GENESIS IMPORTS & EXPORTS LLC

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.

ACTIVE INGREDIENT

Sodium Fluoride .34%

PURPOSE

Anticavity

USE

Helps protect against cavities

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.

Keep out of the reach of children under 6 years of age. if more than the 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: use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)

children under 2 years L ask a dentist or physician

water, hydrated silica, blue, sodium lauryl sulfate, cellulosa gum, sacchharin sodium, xanathan gum, titanium dioxide, glycerin, aroma,green #7, eugenol

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69772-105	
Route of Administration	DENTAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.32 mg in 1 mL	
Inactive Ingredients				
	Ingredient Name		Strength	
	SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
	XANTHAN GUM (UNII: TTV12P4NEE)			
	GLYCERIN (UNII: PDC6A3C0OX)			
	HYDRATED SILICA (UNII: Y6O7T4G8P9)			
	WATER (UNII: 059QF0K00R)			
	FD&C BLUE NO. 1 (UNII: HBR47K3TBD)			
	SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
	CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)			
	PIGMENT GREEN 7 (UNII: BPO9294G4W)			
	EUGENOL (UNII: 3T8H1794QW)			
Product Characteristics				
Color	green, white	Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69772-105-01	4 in 1 PACKAGE	04/17/2017	
1		150 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69772-105-02	150 mL in 1 TUBE; Type 0: Not a Combination Product	04/17/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	04/17/2017		

Labeler - GENESIS IMPORTS & EXPORTS LLC (078760958)

Registrant - TERESA CECENA (078760958)

Establishment

Name	Address	ID/FEI	Business Operations
GENESIS IMPORTS & EXPORTS LLC		078760958	relabel(69772-105)

Establishment

Name	Address	ID/FEI	Business Operations
MISSION HILLS SA DE CV		812312122	manufacture(69772-105)

Revised: 4/2017

GENESIS IMPORTS & EXPORTS LLC