CREST ANTI-CAVITY- 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 .243% (.15% w/v flouride ion)

Purpose

Anticavity toothpaste

WARNINGS AND PRECAUTIONS

KEEEP OUT OF REACH OF CHILDREN UNDER 6 YRS OF AGE

KEEP OUT OF THE CHILDREN UNDER 6 YRS OF AGE.

If more than used for brishing is accidentally swallowed, get medical help or contact a poison control center rigth away.

DIRECTIONS

- adults and children 2 yrs & older; brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist
- do not swallow
- to minimize swallowing use a pea-sides amount in children under 6
- supervise children's brushiong until goog habits are established
- children under 2 yrs ask a dentist

INACTIVE INGREDIENTS:

sorbitol,water,hydrated silica, sodium lauryl sulfate, trisosium phosphate, flavor, sodium phospahte, cellulose gum, sodium saccharin, carbomer, titanium dioxide

USE

Helps protect against cavities

KEEP OUT OF REACH OF CHILDREN UNDER 6 YTS OF AGE

Drug Facts

Active ingredient Purpose
Sodium fluoride 0.243% (0.15% w/v fluoride ion).....Anticavity toothpaste

Use helps protect against cavities

Keep out of reach of children under 6 yrs, 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 yrs, & older: brush teeth thoroughly after meals

Drug Facts (continued)

or at least twice a day or use as directed by a dentist

• do not swallow

• to minimize swallowing use a pea-sized amount in children under 6

• supervise children's brushing until good habits are established

• children under 2 yrs.: ask a dentist

Inactive ingredients sorbitol, water, hydrated silica, sodium lauryl sulfate, trisodium phosphate, flavor, sodium phosphate, cellulose gum, sodium saccharin, carbomer, titanium dioxide

Questions? 1-800-543-7270

Dist, by Procter & Gamble, Cincinnati OH 45202 www.crest.com

UPG Placement VEPISION A AREARDANAUGE QUIET ZONE

37000 22921 6



NET WITBES OZ (99 g)



Regular Paste



FLUORIDE ANTICAVITY TOOTHPASTIE NET WIT 3.5 OZ (99 g)





Regular Paste

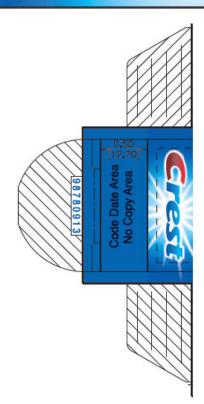


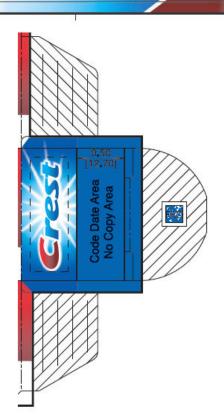
FLUORIDE ANTICAVITY TOOTHPASTIE

NET WIT 3.5 OZ (99 g)



Regular Paste





CREST ANTI-CAVITY

sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69772-130
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	1.45 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
EUGENOL (UNII: 3T8H1794QW)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
SO DIUM PHO SPHATE (UNII: SE337SVY37)		
SORBITOL (UNII: 506T60A25R)		
WATER (UNII: 059QF0KO0R)		
HYDRATED SILICA (UNII: Y6O7T4G8P9)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor	PEPPERMINT	Imprint Code		
Contains				

	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:69772-130-01	1 in 1 CARTON	03/31/2017	
l	1	100 mL 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	03/31/2017			

Registrant - GENESIS IMPORTS & EXPORTS LLC (078760958)

Establishment					
Name	Address	ID/FEI	Business Operations		
genesis imports & exports llc		078760958	relabel(69772-130)		

Establishment				
Name	Address	ID/FEI	Business Operations	
Procter & Gamble Manufactura, S. de R.L. de C.V.		812807550	manufacture(69772-130)	

Revised: 3/2017 GENESIS IMPORTS & EXPORTS LLC