BRISA TROPICAL FRESH- sodium fluoride paste, dentifrice Haney, Inc.

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.

Brisa Tropical Fresh

Drug Facts

Sodium fluoride 0.243% (0.15% w/v fluoride ion)

Purpose

Anticavity toothpaste

Use

helps protect against cavities

Warning

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 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

water, sorbitol, hydrated silica, disodium pyrophosphate, sodium lauryl sulfate, flavor, cellulose gum, sodium hydroxide, sodium saccharin, carbomer, cocos nucifera (coconut) oil, sucralose, polysorbate 80, titanium dioxide

Questions?

1-888-654-6409 DISTR. BY/POR AGILE PURSUITS CINCINNATI, OH 45202

116g tube in carton

brisa[™]
TOOTHPASTE
flouride toothpaste
Tropical Fresh



BRISA TROPICAL FRESH

sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73378-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
l	SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.5 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
CARBOXYPOLYMETHYLENE (UNII: 0 A5MM307FC)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
HYDRATED SILICA (UNII: Y6O7T4G8P9)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)		
COCONUT OIL (UNII: Q9L0O73W7L)		
SORBITOL (UNII: 506T60A25R)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
SODIUM HYDRO XIDE (UNII: 55X04QC32I)		
SODIUM ACID PYROPHOSPHATE (UNII: H5WVD9LZUD)		
WATER (UNII: 059QF0KO0R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:73378-001-41	1 in 1 CARTON	10/21/2019		
1		116 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	10/21/2019			

Labeler - Haney, Inc. (788699445)

Revised: 10/2019 Haney, Inc.