

**BRISA AWAKEN REFRESHED- 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 Awaken Refreshed

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, sodium hydroxide, cellulose gum, sodium saccharin, carbomer, polysorbate 80, mica, titanium dioxide, blue 1

Questions?

1-888-654-6409

DISTR. BY/POR AGILE PURSUITS

CINCINNATI, OH 45202

116g tube in carton

brisa™

TOOTHPASTE
 flouride toothpaste
 Awaken Refreshed



NET WT 4.1OZ (116g)

BRISA AWAKEN REFRESHED

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73378-002
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SORBITOL (UNII: 506T60A25R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM ACID PYROPHOSPHATE (UNII: H5WVD9LZUD)	
WATER (UNII: 059QF0K00R)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
MICA (UNII: V8A1AW0880)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73378-002-41	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.