

**BRISA LUMINOUS WHITENING- 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 Luminous Whitening

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, 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
 Luminous Whitening
 NET WT 4.1OZ (116g)



| BRISA LUMINOUS WHITENING | | | |
|--|------------------------|---------------------------|-----------------|
| sodium fluoride paste, dentifrice | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73378-003 |
| 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: 0A5MMB07FC) | |
| 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) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |

Product Characteristics

| | | | |
|----------|-------|--------------|--|
| Color | white | Score | |
| Shape | | Size | |
| Flavor | MINT | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:73378-003-41 | 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)