

KINDFILL- cinnamon toothpaste tablets tablet, chewable
Make USA 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.

MAKE USA- BYHUMANKIND: Cinnamon Flavor

Active Ingredient(s)

Sodium Fluoride .62mg (28 mg flouride ion)

Purpose

Anti-cavity

Use

aids in the prevention of dental cavities

Warnings

- When using this product, if irritation or sensitivity occurs discontinue use.
- Keep out of the reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

When using this product, if irritation or sensitivity occurs discontinue use.

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- Adults and children 6 years of age and older; chew one tablet until crushed, wet toothbrush, brush for 2 minutes. Spit out.
- Do not swallow the tablet.
- Children under 6 years of age should be supervised when using this product.

Other information

Store at 25-30°C (68-77°F). Protect from excessive moisture.

Inactive ingredients

Microcrystalline Cellulose, Sodium bicarbonate (Baking Soda), Silica, Sodium Lauryl Glutamate, Magnesium Stearate, Xanthan Gum, Stevia (Stevioside), Citric Acid

Package Label - Principal Display Panel

| <p>Kindfill™</p> <p>Cinnamon Toothpaste TABLETS</p> <p>by Humankind</p> <p>CONTAINS FLUORIDE NET WT. — 60 TABLETS 18.0 G. / 0.65 OZ.</p> | <p>Cinnamon</p> <p>Toothpaste TABLETS</p> <p>DIRECTIONS Adults and children 6 years of age and older: Chew 1 TABLET until crushed; Wet toothbrush; Brush for 2 MINUTES; Spit out; Do not swallow the tablet. Children under 6 years of age should be supervised when using this product.</p> <p>PACKAGE 100% compostable materials; compost where accepted.</p> | <p>LOT NO. G0921</p> <p>EXPIRY 09/22</p> <p>Tablets manufactured in Germany by Denttabs GmbH</p> <p>Package made in CN by Humankind, Inc.</p> <p>Dist. by Humankind 6 St. Johns Lane New York, NY 10013</p> <p>@byHumankind byHumankind.com</p> | <table border="1"> <tr> <th colspan="2">Drug Facts (in each tablet)</th> </tr> <tr> <td>Active Ingredient</td> <td>Purpose</td> </tr> <tr> <td>Sodium Fluoride .62 mg (.28 mg fluoride ion) . . .</td> <td>Anti-cavity</td> </tr> <tr> <td colspan="2">Uses Aids in the prevention of dental cavities.</td> </tr> <tr> <td colspan="2">Warnings</td> </tr> <tr> <td colspan="2">When using this product, if irritation or sensitivity occurs, discontinue use.</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.</td> </tr> <tr> <td colspan="2">Directions</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> Adults and children 6 years of age and older: Chew tablet briefly and brush thoroughly. Brush for 2 minutes; Spit out; Do not swallow the tablet. Children under 6 years of age should be supervised when using this product. </td> </tr> <tr> <td colspan="2">Other information</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> Store at 25–30°C (68–77°F). Protect from excessive moisture. </td> </tr> <tr> <td colspan="2">Inactive ingredients</td> </tr> <tr> <td colspan="2">Microcrystalline cellulose; Sodium bicarbonate; Silica; Sodium lauryl glutamate; Magnesium stearate; Cinnamon Cassia Leaf Oil; Xanthan gum; Stevia; Citric acid.</td> </tr> </table> | Drug Facts (in each tablet) | | Active Ingredient | Purpose | Sodium Fluoride .62 mg (.28 mg fluoride ion) . . . | Anti-cavity | Uses Aids in the prevention of dental cavities. | | Warnings | | When using this product , if irritation or sensitivity occurs, discontinue use. | | Keep out of reach of children . If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately. | | Directions | | <ul style="list-style-type: none"> Adults and children 6 years of age and older: Chew tablet briefly and brush thoroughly. Brush for 2 minutes; Spit out; Do not swallow the tablet. Children under 6 years of age should be supervised when using this product. | | Other information | | <ul style="list-style-type: none"> Store at 25–30°C (68–77°F). Protect from excessive moisture. | | Inactive ingredients | | Microcrystalline cellulose; Sodium bicarbonate; Silica; Sodium lauryl glutamate; Magnesium stearate; Cinnamon Cassia Leaf Oil; Xanthan gum; Stevia; Citric acid. | |
|--|---|---|---|-----------------------------|--|--------------------------|----------------|--|-------------|--|--|-----------------|--|--|--|---|--|-------------------|--|--|--|--------------------------|--|---|--|-----------------------------|--|--|--|
| Drug Facts (in each tablet) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Active Ingredient | Purpose | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Sodium Fluoride .62 mg (.28 mg fluoride ion) . . . | Anti-cavity | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Uses Aids in the prevention of dental cavities. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Warnings | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| When using this product , if irritation or sensitivity occurs, discontinue use. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Keep out of reach of children . If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Directions | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <ul style="list-style-type: none"> Adults and children 6 years of age and older: Chew tablet briefly and brush thoroughly. Brush for 2 minutes; Spit out; Do not swallow the tablet. Children under 6 years of age should be supervised when using this product. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Other information | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <ul style="list-style-type: none"> Store at 25–30°C (68–77°F). Protect from excessive moisture. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inactive ingredients | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Microcrystalline cellulose; Sodium bicarbonate; Silica; Sodium lauryl glutamate; Magnesium stearate; Cinnamon Cassia Leaf Oil; Xanthan gum; Stevia; Citric acid. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

60 in Each Box NDC: 80486-113-11

| KINDFILL | | | |
|--|-------------------|---------------------------|---------------|
| cinnamon toothpaste tablets tablet, chewable | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:80486-113 |
| Route of Administration | DENTAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) | SODIUM FLUORIDE | 0.62 mg in 312 mg | |
| Inactive Ingredients | | | |
| Ingredient Name | Strength | | |
| STEVIA LEAF (UNII: 6TC6NN0876) | | | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | | | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | | | |
| MINT (UNII: FV98Z8GITP) | | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | | |
| SODIUM LAUROYL GLUTAMATE (UNII: NCX1UU2D33) | | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | | |

| Product Characteristics | | | |
|-------------------------|----------|--------------|----------|
| Color | white | Score | no score |
| Shape | ROUND | Size | 10mm |
| Flavor | CINNAMON | Imprint Code | NONE |
| Contains | | | |

| Packaging | | | | |
|-----------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:80486-113-11 | 60 in 1 BOX | 09/29/2021 | |
| 1 | | 312 mg in 1 BOX, UNIT-DOSE; 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 | 09/29/2021 | |

Labeler - Make USA LLC (110142615)

| Establishment | | | |
|---------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| Make USA LLC | | 110142615 | repack(80486-113) |

| Establishment | | | |
|---------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Denttabs GmbH | | 340109625 | manufacture(80486-113) |

Revised: 9/2021

Make USA LLC