

KINDFILL- mint toothpaste tablets tablet, chewable
By Humankind 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.

BYHUMANKIND- Identipack: Kindfill Mint

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.

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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, Natural Mint Flavor, Menthol, Xanthan Gum, Stevia (Stevioside), Citric Acid

Package Label - Principal Display Panel

<p>Kindfill™</p> <p><i>Mint</i> Toothpaste TABLETS</p> <p>by Humankind</p> <p>CONTAINS FLUORIDE NET WT. — 60 TABLETS 18.0 G. / 0.65 OZ.</p>	<p><i>Mint</i></p> <p>Toothpaste TABLETS</p> <p>DIRECTIONS Adults and children 6 years of age and older: Chew 1 TABLET until crushed; Wet tooth- brush; Brush for 2 MINUTES; Spit out; Do not swallow the tab- let. 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.</p> <p>EXPIRY</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 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. </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; Natural mint flavor; Menthol; 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 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. 		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; Natural mint flavor; Menthol; Xanthan gum; Stevia; Citric acid.	
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60 in Each Box NDC: 80487-311-11

KINDFILL			
mint toothpaste tablets tablet, chewable			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80487-311(NDC:68984-122)
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		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
STEVIA LEAF (UNII: 6TC6NN0876)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
SODIUM BICARBONATE (UNII: 8MDF5V39QO)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
MINT (UNII: FV98Z8GITP)			
MENTHOL, (+)- (UNII: C6B10E8P3W)			
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	PEPPERMINT	Imprint Code	NONE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80487-311-11	60 in 1 BOX	01/05/2023	
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	01/05/2023	

Labeler - By Humankind Inc (117642980)

Establishment

Name	Address	ID/FEI	Business Operations
Identipak, Inc		942862350	repack(80487-311)

Revised: 1/2023

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