

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-MAKE USA: Kindfill Dental Tabs**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><i>by</i> Humankind</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 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.</p> <p>EXPIRY</p> <p>Tablets manufactured in Germany by Denttabs gmbH</p> <p>Package made in CN <i>by</i> Humankind, Inc.</p> <p>Dist. <i>by</i> Humankind 6 St. Johns Lane New York, NY 10013</p> <p><i>@byHumankind</i> <i>byHumankind.com</i></p>	<p>Drug Facts (in each tablet)</p> <hr/> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Active Ingredient</td> <td style="width: 40%;">Purpose</td> </tr> <tr> <td>Sodium Fluoride .62 mg (.28 mg fluoride ion) . . .</td> <td>Anti-cavity</td> </tr> </table> <hr/> <p>Uses Aids in the prevention of dental cavities.</p> <hr/> <p>Warnings</p> <p>When using this product, if irritation or sensitivity occurs, discontinue use.</p> <hr/> <p>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.</p> <hr/> <p>Directions</p> <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. <hr/> <p>Other Information</p> <ul style="list-style-type: none"> • Store at 25-30°C (68-77°F). • Protect from excessive moisture. <hr/> <p>Inactive ingredients Microcrystalline cellulose; Sodium bicarbonate; Silica; Sodium lauryl glutamate; Magnesium stearate; Natural mint flavor; Menthol; Xanthan gum; Stevia; Citric acid.</p>	Active Ingredient	Purpose	Sodium Fluoride .62 mg (.28 mg fluoride ion) . . .	Anti-cavity
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Sodium Fluoride .62 mg (.28 mg fluoride ion) . . .	Anti-cavity						

60 in Each Box NDC:80487-112-11

KINDFILL			
mint toothpaste tablets tablet, chewable			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80487-112
Route of Administration	DENTAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	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: FV98Z8G1TP)			
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	10 mm

Flavor	PEPPERMINT	Imprint Code	NONE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80487-112-11	60 in 1 BOX	02/09/2021	
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	10/22/2020	

Labeler - By Humankind Inc (117642980)

Establishment

Name	Address	ID/FEI	Business Operations
Make USA LLC		110 1426 15	repack(80487-112)

Establishment

Name	Address	ID/FEI	Business Operations
Denttabs GmbH		340 1096 25	manufacture(80487-112)

Revised: 2/2021

By Humankind Inc