

KINDFILL- mint 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: Kindfill Dental Tabs

Active Ingredient(s)

Sodium Fluoride .45mg (11.8 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



60 in Each Box NDC: 80486-111-11

KINDFILL

mint toothpaste tablets tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80486-111
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.45 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	10mm
Flavor	PEPPERMINT	Imprint Code	NONE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80486-111-11	60 in 1 BOX	10/22/2020	
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 - Make USA LLC (110142615)**Establishment**

Name	Address	ID/FEI	Business Operations
Make USA LLC		110 1426 15	repack(80486-111)

Establishment

Name	Address	ID/FEI	Business Operations
Denttabs GmbH		340 1096 25	manufacture(80486-111)

Revised: 10/2020

Make USA LLC