

KAYLAAN- zero waste refill for toothpaste tablet, chewable
Kaylaan 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.

Kaylaan Mint Toothpaste Tablet

Dosage & Administration

- Adults and Children 6 years of age and older: Crunch 1 tablet briefly and brush teeth thoroughly. Do not swallow the tablet.
- Supervise children under 6 years of age for brushing and rinsing.

Warnings

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

Inactive Ingredients Calcium Carbonate, Erythritol, Magnesium Stearate, Natural extract
Mint, Sodium Bicarbonate, Sodium Cocoyl Isethionate, Stevia, Xanthan Gum, Xylitol

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Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact the Poison Control Center immediately.

Uses aids in the prevention of dental cavities

Drug Facts

Active Ingredients (in each Tablet)

Sodium Fluoride 0.82 mg (0.37 mg fluoride ion).....

Purpose

.....Anti-Cavity

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<ul style="list-style-type: none"> • Adults and Children 6 years of age and older: Crunch 1 tablet briefly and brush teeth thoroughly. Do not swallow the tablet. • Supervise children under 6 years of age for brushing and rinsing. 	
Other information: Store below 77 degree F and protect from excessive moisture.	
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82091-112
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.37 mg in 440 mg

Inactive Ingredients

Ingredient Name	Strength
STEVIA LEAF (UNII: 6TC6NN0876)	
ERYTHRITOL (UNII: RA96B954X6)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MINT (UNII: FV98Z8GITP)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	5mm
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82091-112-10	74.3 mg in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	09/13/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/13/2021	

Labeler - Kaylaan LLC (077425217)

Establishment

Name	Address	ID/FEI	Business Operations
Kaylaan LLC		077425217	manufacture(82091-112)

