

**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.*

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**Kaylaan Blueberry Toothpaste Tablet Refill**

***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

**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.

**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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<b>Uses</b>	aids in the prevention of dental cavities
<b>Warnings</b>	
When using this product, if irritation or sensitivity occurs, discontinue use.	
<b>Keep out of reach of children.</b> If more than used for brushing is accidentally swallowed, get medical help or contact the Poison Control Center immediately.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• Adults and Children 6 years of age and older: Crunch 1 tablet briefly and brush teeth thoroughly. Do not swallow the tablet.</li> <li>• Supervise children under 6 years of age for brushing and rinsing.</li> </ul>	
<b>Other information: Store</b> below 77 degree F and protect from excessive moisture.	
<b>Inactive Ingredients</b> Calcium Carbonate, Erythritol, Magnesium Stearate, Natural extract Mint, Sodium Bicarbonate, Sodium Cocoyl Isethionate, Stevia, Xanthan Gum, Xylitol	

# KAYLAAN

zero waste refill for toothpaste tablet, chewable

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82091-114
<b>Route of Administration</b>	DENTAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>STEVIA LEAF</b> (UNII: 6TC6NN0876)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>BLUEBERRY</b> (UNII: 253RUG1X1A)	
<b>ERYTHRITOL</b> (UNII: RA96B954X6)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM COCOYL ISETHIONATE</b> (UNII: 518XTE8493)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	5mm
<b>Flavor</b>	BLUEBERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82091-114-01	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(82091-114)

