

**KAYLAAN- zero waste refill for toothpaste tablet, chewable**  
**Kaylaan LLC**

-----  
**Kaylaan Watermelon Toothpaste Tablet Refill**

**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

**Uses** aids in the prevention of dental cavities

**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

<b>Drug Facts</b>	
<b>Active Ingredients (in each Tablet)</b>	<b>Purpose</b>
Sodium Fluoride 0.82 mg (0.37 mg fluoride ion).....	Anti-Cavity
<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:</b> Store 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:82091-116
<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>ERYTHRITOL</b> (UNII: RA96B954X6)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>SODIUM COCOYL ISETHIONATE</b> (UNII: 518XTE8493)	
<b>STEVIA LEAF</b> (UNII: 6TC6NN0876)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>WATERMELON</b> (UNII: 231473QB6R)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82091-116-01	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 Drug	M022	09/13/2021	

**Labeler** - Kaylaan LLC (077425217)

## Establishment

Name	Address	ID/FEI	Business Operations
Kaylaan LLC		077425217	manufacture(82091-116)

