

**TOOTHPASTETABLETS- toothpaste tablets tablet**  
**HONG KONG DAILYGREEN TRADE CO., LIMITED**

*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.*

-----  
**83525-001**  
**Toothpaste Tablets**

**Active ingredient**

Sodium Monofluorophosphate 0.877% (1100ppm w/v fluoride ion)

**Purpose**

Anticavity Toothpaste

**Use**

aids in the prevention of dental cavities

**Warnings**

Keep out of reach of children. Not to be used by children under 12 years of age. If more than used for brushing is accidentally swallowed get medical help or contact a Poison Control Center right away.

Not to be used by children under 12 years of age.

If more than used for brushing is accidentally swallowed get medical help or contact a Poison Control Center right away.

Keep out of reach of children.

**Directions**

Adults: Wet your toothbrush and crush the tab between your teeth.

Brush like normal. Rinse after using.

Brush teeth thoroughly preferably after each meal or at least twice a day or as directed by a dentist or physician. Do not swallow

**Other Information**

Store at room temperature and dry place.

**Inactive ingredients**

Sorbitol, Calcium Carbonate, Probiotics, Xylitol, Magnesium Stearate, Stevia Rebaudiana Extract,  
Tea (Camellia Sinensis) Polyphenols, Peppermint (Mentha Piperita) Oil, Bitter Orange (Citrus Aurantium) Flower Oil,  
Peppermint (Mentha Piperita) Leaf Oil, Cocamidopropyl Betaine.

## Questions?

Call (619) 940-6502

83525-001-01



295mm

83525-001-11

lid of size  
119.32\*H70mm



tube of size  
119.32\*H23mm



Top



Bottom

Neck of part  
119.32\*H70mm



D38mm

if you add a logo on the top and bottom, it should be smaller than 28mm.

The size will have a little error, tolerance.

## TOOTHPASTETABLETS

toothpaste tablets tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83525-001
<b>Route of Administration</b>	PERIODONTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.877 g in 100

### Inactive Ingredients

Ingredient Name	Strength
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>CAMELLIA SINENSIS WHOLE</b> (UNII: C5M4585ZBZ)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>STEVIA REBAUDIANA WHOLE</b> (UNII: 6U422Y08O2)	

<b>COCO/OLEAMIDOPROPYL BETAINE</b> (UNII: 5M84PX7JN2)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>HEDEOMA PULEGIOIDES LEAF OIL</b> (UNII: 3Z236RKQ9N)	
<b>CITRUS AURANTIUM FLOWER OIL</b> (UNII: D4BGE91OXH)	
<b>MENTHA SPICATA OIL</b> (UNII: C3M81465G5)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	12mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	no
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83525-001-01	6 in 1 BOX	06/09/2023	
1	NDC:83525-001-11	60 in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/09/2023	

**Labeler** - HONG KONG DAILYGREEN TRADE CO., LIMITED (655740805)

### Establishment

Name	Address	ID/FEI	Business Operations
HONG KONG DAILYGREEN TRADE CO., LIMITED		655740805	manufacture(83525-001) , label(83525-001)

Revised: 6/2023

HONG KONG DAILYGREEN TRADE CO., LIMITED