

TOOTH- toothpaste tablets tablet
Henan Dailygreen Biotechnology Co. LTD

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

83861-003

Active ingredient

Sodium Fluoride 0.925% (1445ppm w/v fluoride ion)

Purpose

Anti-cavity

Use

aids in the prevention of dental cavities

Warnings

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

N/A

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

n/a

Keep out of reach of children.

If more than used for brushing is accidentally swallowed, get medical help or contact a poison Control Center immediately.

Directions

- Adults and children 6 years of age and older; Chew tablet briefly and brush thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Do not swallow the tablet.
- Supervise children under 6 years of age for brushing and rinsing.

Other Information

Store at 25-30°C (68-77°F). Protect from excessive moisture.

Inactive ingredients

Xylitol, Sodium Cocoyl Isethionate (made from coconut), Microcrystalline Cellulose, Calcium Carbonate, Sodium Bicarbonate, Erythritol, Natural Mint, Sodium Fluoride, Guar Gum



TOOTH

toothpaste tablets tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:83861-003

Route of Administration

PERIODONTAL

Active Ingredient/Active Moiety

Ingredient Name

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)

Basis of Strength

FLUORIDE ION

Strength

0.925 mg in 100

Inactive Ingredients

Ingredient Name

SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)

Strength

Ingredient Name

GUAR GUM (UNII: E89I1637KE)

Strength

CALCIUM CARBONATE (UNII: H0G9379FGK)	
MINT (UNII: FV98Z8GITP)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ERYTHRITOL (UNII: RA96B954X6)	

Product Characteristics

Color	white	Score	score with uneven pieces
Shape	ROUND	Size	11mm
Flavor	MINT (Mint, citrus, cinnamon mixed flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83861-003-01	180 in 1 BAG; Type 0: Not a Combination Product	11/19/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/19/2024	

Labeler - Henan Dailygreen Biotechnology Co. LTD (699305250)

Registrant - Henan Dailygreen Biotechnology Co. LTD (699305250)

Establishment

Name	Address	ID/FEI	Business Operations
Henan Dailygreen Biotechnology Co. LTD		699305250	manufacture(83861-003)

Revised: 11/2024

Henan Dailygreen Biotechnology Co. LTD