

FLUORIDE- toothpaste tablets tablet, chewable
Henan Dailygreen Trade Co.,Ltd.

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.

Fluoride Toothpaste Tablets

Active ingredient

Sodium Fluoride 0.145%

Purpose

Anticaries

Uses

Aids in the prevention of dental cavities

Warnings

- Keep out of reach of children under 6 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 under 6 years of age.

Directions

1. Chew: Place tablet in mouth and chew for 5 seconds.
2. Hydrate: Use a wet brush to moisten the toothpaste in your mouth and brush teeth.
3. Brush: Brush for at least 30 seconds. Rinse and spit out thoroughly. Brush teeth, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: Do not use unless directed by a dentist or doctor.

Other Information

Store in room temperature. Avoid direct sunlight.

Shelf life: 3 years.

Production Date: as shown in the packing

Website: www.dailygreen.en.alibaba.com

Inactive Ingredients

Microcrystalline Cellulose, Xylitol, Erythritol, Natural Mint Flavor, Calcium Carbonate, Sodium Cocoyl Isethionate, Sodium Bicarbonate, Laurel Extract, Cooling Oil

60 tablets / glass bottle: NDC: 80143-001-01

62 tablets / glass bottle: NDC: 80143-001-02

120 tablets / glass bottle: NDC: 80143-001-03



60 tablets / paper tube: NDC: 80143-001-04

90 tablets / paper tube: NDC: 80143-001-05

120 tablets / paper tube: NDC: 80143-001-06



30 tablets / carton: NDC: 80143-001-07

60 tablets / carton: NDC: 80143-001-08



2 tablets / bag: NDC: 80143-001-09

62 tablets / bag: NDC: 80143-001-10

120 tablets / bag: NDC: 80143-001-11

1000 tablets / bag: NDC: 80143-001-12



FLUORIDE

toothpaste tablets tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80143-001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.00145

Inactive Ingredients

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	0.51012
OLEIC ACID (UNII: 2UMI9U37CP)	0.005
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.03
CALCIUM CARBONATE (UNII: H0G9379FGK)	0.05
SODIUM ISETHIONATE (UNII: 3R36J71C17)	0.3
ERYTHRITOL (UNII: RA96B954X6)	0.03
RACEMENTHOL (UNII: YS08XHA860)	0.00343
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	0.06
MYRCENE (UNII: 3M39CZS25B)	0.01

Product Characteristics

Color	white (None)	Score	score with uneven pieces
Shape	ROUND (None)	Size	11mm
Flavor	MINT (None)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80143-001-01	60 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	06/24/2020	
2	NDC:80143-001-02	62 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	06/24/2020	
3	NDC:80143-001-03	120 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	06/24/2020	
4	NDC:80143-001-04	60 in 1 TUBE; Type 0: Not a Combination Product	06/24/2020	
5	NDC:80143-001-05	90 in 1 TUBE; Type 0: Not a Combination Product	06/24/2020	
6	NDC:80143-001-06	120 in 1 TUBE; Type 0: Not a Combination Product	06/24/2020	
7	NDC:80143-001-07	30 in 1 CARTON; Type 0: Not a Combination Product	06/24/2020	
8	NDC:80143-001-08	60 in 1 CARTON; Type 0: Not a Combination Product	06/24/2020	
9	NDC:80143-001-09	2 in 1 BAG; Type 0: Not a Combination Product	06/24/2020	
10	NDC:80143-001-10	62 in 1 BAG; Type 0: Not a Combination Product	06/24/2020	
11	NDC:80143-001-11	120 in 1 BAG; Type 0: Not a Combination Product	06/24/2020	
12	NDC:80143-001-12	1000 in 1 BAG; Type 0: Not a Combination Product	06/24/2020	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/24/2020	

Labeler - Henan Dailygreen Trade Co.,Ltd. (554544781)

Registrant - Henan Dailygreen Trade Co.,Ltd. (554544781)

Establishment

Name	Address	ID/FEI	Business Operations
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Henan Dailygreen Trade Co.,Ltd.		554544781	manufacture(80143-001) , label(80143-001) , pack(80143-001)
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Revised: 12/2021

Henan Dailygreen Trade Co.,Ltd.