

**UNPASTE- zero waste fluoride cinnamon tooth tabs tablet, chewable
Farmina sp. z.o.o.**

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.

Farmina Cinnamon Tabs

Active Ingredient(s)

Sodium Fluoride 0.62mg (28 mg flouride ion)

Purpose

Anti-cavity

Use

aids in the prevention of dental cavities

Warnings

- When using this product, if irritation or sensitivity occurs discontinue use.
- Keep out of the reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

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Directions

- Adults and children 6 years of age and older; chew one tablet briefly and brush teeth 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

Microcrystalline Cellulose, Sodium bicarbonate (Baking Soda), Silica, Sodium Lauryl Glutamate, Magnesium Stearate, Natural Mint Flavor, Xanthan Gum, Stevia (Stevioside),

Citric Acid

Package Label - Principal Display Panel

PRINCIPAL DISPLAY PANEL – Product in bulk shipping label

Unpaste – zero-waste fluoride cinnamon tooth tabs, chewable tablets

Unpaste – cynamonowe tabletki do mycia zębów z fluorem

Each tablet contains: 0,62 mg Sodium fluoride

Każda tabletka zawiera: 0,62 mg fluorku sodu

NDC no.: 68984-121-04

NDC numer: 68984-121-04

Lot no.:

Nr serii:

Mfg date: (DDMMYYYY)

Data produkcji:

Net weight: kg

Waga netto:

Drum no.

Nr beczki:

STORE AT CONTROLLED ROOM TEMPERATURE OF 59 -77 F (15 – 25 C)

PROTECT FROM LIGHT, MOISTURE AND FREEZING.

PRZECHOWYWAĆ W KONTROLOWANEJ TEMPERATURZE POKOJOWEJ 59 -77 F (15 -25 C)

CHRONIĆ PRZED ŚWIATŁEM, WILGOCIĄ I ZAMARZANIEM.

Manufactured by:

Wyprodukowane przez:

Farmina Zakład w Myślenicach

Ul. Cegielskiego 2

32 – 400 Myślenice

Manufactured for:

Wyprodukowane dla:

Denttabs innovative Zahnpflegegesellschaft mbH

Gerichtstraße 12-13

13347 Berlin

Delivered to:

Dostarczony do:

PTG Lohnverpackung GmbH

Carl -Zeiss-Straße 19-23

63322 Rödermark

Product code: 6950U

Kod produktu: 6950U

Country of origin: Poland

Kraj pochodzenia: Polska

CAUTION: „FOR MANUFACTURING, PROCESSING OR REPACKING”

UWAGA: “DO PRODUKCJI, PRZETWARZANIA LUB PRZEPAKOWANIA”

120 kg Drum, NDC: 68984-121-04

UNPASTE

zero waste fluoride cinnamon tooth tabs tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68984-121
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.62 mg

Inactive Ingredients

Ingredient Name	Strength
STEVIA LEAF (UNII: 6TC6NN0876)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MINT (UNII: FV98Z8GITP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM LAUROYL GLUTAMATE (UNII: NCX1UU2D33)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	10mm
Flavor	PEPPERMINT	Imprint Code	NONE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68984-121-04	380000 in 1 DRUM; Type 0: Not a Combination Product	01/10/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/10/2022	

Labeler - Farmina sp. z.o.o. (422254391)

Establishment

Name	Address	ID/FEI	Business Operations
Farmina sp. z o.o., Zakład w Myslenicach		849477431	manufacture(68984-121)

Revised: 5/2023

Farmina sp. z.o.o.