

**UNPASTE- zero waste fluoride mint 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 Mint 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.

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

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 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, Menthol, Xanthan Gum, Stevia

(Stevioside), Citric Acid

## Package Label - Principal Display Panel

PRINCIPAL DISPLAY PANEL – Product in bulk shipping label

### Unpaste – zero-waste fluoride mint tooth tabs, chewable tablets

*Unpaste – miętowe tabletki do mycia zębów z fluorem*

Each tablet contains: 0,62 mg Sodium fluoride

*Każda tabletką zawiera: 0,62 mg fluorku sodu*

NDC no.: 68984-122-04

*NDC numer: 68984-122-04*

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”*

120kg drum, NDC: 68984-122-04

## UNPASTE

zero waste fluoride mint tooth tabs tablet, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68984-122
<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)	SODIUM FLUORIDE	0.62 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>STEVIA LEAF</b> (UNII: 6TC6NN0876)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>MINT</b> (UNII: FV98Z8GITP)	
<b>MENTHOL, (+)-</b> (UNII: C6B1OE8P3W)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SODIUM LAUROYL GLUTAMATE</b> (UNII: NCX1UU2D33)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68984-122-04	380000 in 1 DRUM; Type 0: Not a Combination Product	12/01/2022	

## 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(68984-122)

Revised: 5/2023

Farmina sp. z.o.o.