# UNPASTE TOOTH TABS- zero was te replacement for toothpas te tablet, chewable Avespan LLC

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.

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# **Unpaste Tooth Tabs**

# **Active Ingredient(s)**

Sodium Fluoride .45mg (11.8 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.

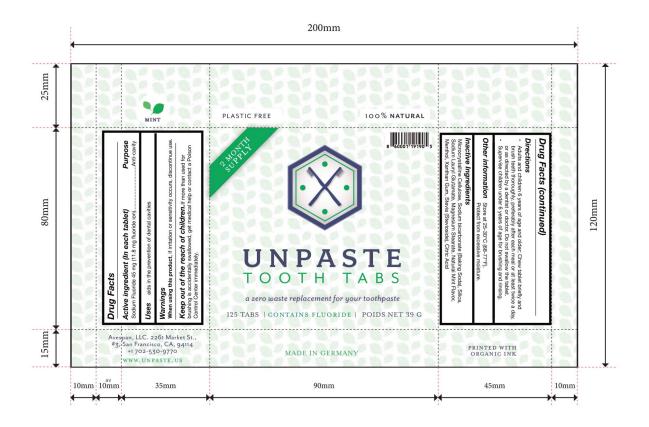
#### Other information

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, Menthol, Xanthan Gum, Stevia (Stevioside), Citric Acid

# Package Label - Principal Display Panel



PLastic Free 100% Natural
2 Months Supply
UNPASTE TOOTH TABS
A zero-waste replacement for your toothpaste
125 TABS Contains Flouride POIDS Net 39G
Made in Germany

#### UNPASTE TOOTH TABS zero waste replacement for toothpaste tablet, chewable **Product Information** Product Type HUMAN OTC DRUG Item Code (Source) NDC:74355-111 **Route of Administration DENTAL Active Ingredient/Active Moiety Basis of Strength Ingredient Name** Strength **SODIUM FLUORIDE** (UNII: 8 ZYQ 1474W7) (FLUORIDE ION - UNII:Q80 VPU408O) SODIUM FLUORIDE 0.45 mg in 312 mg

Inactive Ingredients		
Ingredient Name	Strength	
STEVIA LEAF (UNII: 6TC6NN0876)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
SODIUM BICARBONATE (UNII: 8MDF5V39QO)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
MINT (UNII: FV98Z8GITP)		
<b>MENTHOL, (+)-</b> (UNII: C6B1OE8P3W)		
XANTHAN GUM (UNII: TTV12P4NEE)		
SODIUM LAURO YL GLUTAMATE (UNII: NCX1UU2D33)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		

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

I	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:74355-111- 01	125 in 1 PACKET	05/15/2020		
	1	312 mg in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/15/2020	

# Labeler - Avespan LLC (117415511)

Establishment			
Name	Address	ID/FEI	Business Operations
Denttabs GmbH		340109625	manufacture(74355-111)

Revised: 5/2020 Avespan LLC