UNPASTE- zero waste fluoride mint tooth tabs 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.

Avespan-PTG Mint 2023

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.

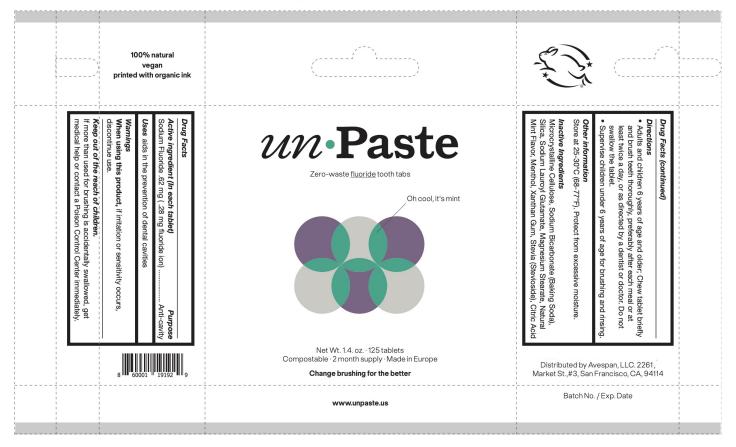
Other information

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, Menthol, Xanthan Gum, Stevia

Package Label - Principal Display Panel



125 tabs, NDC: 74355-322-02

UNPASTE

zero waste fluoride mint tooth tabs tablet, chewable

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74355-322(NDC:68984-122)	
Route of Administration	DENTAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	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)			
MENTHOL, (+)- (UNII: C6B1OE8P3W)			
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				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:74355-322- 01	10 in 1 PACKAGE; Type 0: Not a Combination Product	05/01/2023		
2	NDC:74355-322- 02	125 in 1 PACKAGE; Type 0: Not a Combination Product	05/01/2023		
3	NDC:74355-322- 03	10000 in 1 PACKAGE; Type 0: Not a Combination Product	05/01/2023		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/01/2023	

Labeler - Avespan LLC (117415511)

Establishment				
Name	Address	ID/FEI	Business Operations	
PTG Lohnabfuellung GmbH		331962873	repack(74355-322) , relabel(74355-322)	

Revised: 5/2023 Avespan LLC