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-Farmina Mint 2022

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: 74355-222-01

UNPASTE

zero waste fluoride mint tooth tabs tablet, chewable

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74355-222	
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 in 312 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: C6B10E8P3W)	
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	tem Code Package Description Marketing		Marketing End Date	
1	NDC:74355- 222-01	125 in 1 PACKET	12/01/2022		
1		312 mg in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product			
2	NDC:74355- 222-02	10000 in 1 CARTON	12/01/2022		
2		312 mg in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product			
3	NDC:74355- 222-03	10 in 1 PACKET	12/01/2022		
3		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	12/01/2022	

Labeler - Avespan LLC (117415511)

Establishment				
Name	Address	ID/FEI	Business Operations	
Farmina sp. z o.o., Zaklad w Myslenicach		849477431	manufacture(74355-222)	

Revised: 11/2022 Avespan LLC