

ORAL FUSION ANTICAVITY- sodium fluoride paste, dentifrice
Yangzhou SION Commodity Co.,Ltd

70766-010

Active ingredients

Sodium Fluoride 0.243%

Purpose

anticavity

Uses

Help protect against cavities

Warnings

Keep out of the reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Keep out of reach of children.

Directions

Adult and children 2 years of age and older:

- Brush teeth thoroughly after meal or at least twice a day, or use as directed by a dentist.
- Do not swallow
- To minimizing swallowing, use only a pea sized amount in children under 6
- and supervise children's brushing and rinsing to minimize swallowing.

Under 2 years:

- Ask a dentist

INACTIVE INGREDIENT

Sorbitol, Water, Hydrated Silica, Disodium pyrophosphate, Flavor, Sodium Hydroxide, Xanthan Gum, Cellulose Gum, Hydroxypropyl Guar, Methyl Paraben Sodium, Propyl Paraben Sodium, Sodium Saccharin, Water, Sodium Lauryl Sulfate, CI 778891



Oral Fusion Fluoride Toothpaste

Drug Facts

Active ingredient Purpose
Sodium Fluoride 0.243%..... Anticavity
Toothpaste

Use helps protect against cavities

Warnings

Keep out of reach of children under 6 yrs. of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 2 yrs. & older: brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist
- do not swallow
- to minimize swallowing use a pea-sized amount in children under 6
- supervise children's brushing until good habits are established children under 2 yrs. : ask a dentist

Inactive ingredients

sorbitol,water,hydrated silica,disodium pyrophosphate,sodium lauryl sulfate, flavor,sodium hydroxide,xanthan gum, cellulose gum,hydroxypropyl guar, sodium fluoride,sodium saccharin, methylparaben,propylparaben,Ci 77891

Questions 1-848-888-8889

DISTRIBUTED IN USA BY:
CLICK PRODUCTS LLC
EDISON N.J. 08817
MADE IN CHINA
www.oral-fusion.com

ORAL FUSION ANTICAVITY

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70766-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.11 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
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SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SORBITOL (UNII: 506T60A25R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROXYPROPYL GUAR (2500-4500 MPA.S AT 1%) (UNII: 3A1I7376TC)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70766-010-01	12 in 1 PACKAGE	04/28/2022	
1		24 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70766-010-02	48 in 1 CARTON	04/28/2022	
2		24 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	04/28/2022	

Labeler - Yangzhou SION Commodity Co.,Ltd (546806042)

Registrant - Yangzhou SION Commodity Co.,Ltd (546806042)

Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou SION Commodity Co.,Ltd		546806042	manufacture(70766-010)

Revised: 12/2023

Yangzhou SION Commodity Co.,Ltd