

CHARM-TEX FLUORIDE GEL- sodium fluoride paste, dentifrice
Jiangsu Aimeili Cosmetic Co.,Ltd.

77573-012

Active ingredients

Sodium Fluoride 0.22%(0.1 w/v Fluoride Ion)

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.

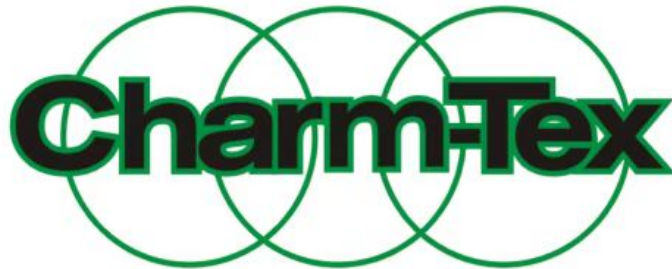
Keep out of reach of children.

Directions

- Adults and children 6 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or a physician.
- Children 2 to 6 years: Use only a pea sized amount and supervise children's brushing and rinsing to minimize swallowing
- Children under 2 years: Ask a dentist or physician

INACTIVE INGREDIENT

Sorbitol, Silica, Calcium Carbonate, Methylparaben Sodium, Propylparaben Sodium, Flavor, Sodium Saccharin, Water, SMC, Sodium Lauryl Sulfate



Net Wt. 0.85 oz.
24 Grams

FLUORIDE GEL TOOTHPASTE

DRUG FACTS		DIRECTIONS
Active ingredient: Sodium Fluoride 0.22%(0.1% w/v fluoride ion)	Purpose Anticavity	Adults and children 6 years of age and older: brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or a physician.
Use: helps protect against cavities.		
Warning: 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 centre immediately.		Children 2 to 6 years: Use only a pea sized amount and supervise child's brushing and rinsing to minimize swallowing.
Inactive Ingredient: Sorbitol, Silica, Methyl Paraben Sodium, Propyl Paraben Sodium, Flavour, Sodium Saccharin, Treated water, SCMC, Sodium Lauryl Sulfate.		
Product of China, Exclusive Distributor: Charm-Tex, Inc. USA, WWW.CHARM-TEX.COM		Children under 2 years: Ask a dentist or physician.

N.C. No.: DD/COS/DD/C/340

Mfg. Date & Batch No. on crimp

Expiry: 2 years from the date of Mfg.

EPL

CHARM-TEX FLUORIDE GEL

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77573-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77573-012-01	1000 in 1 PACKAGE	07/11/2022	
1		7.1 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:77573-012-02	720 in 1 PACKAGE	07/11/2022	
2		17 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:77573-012-03	720 in 1 PACKAGE	07/11/2022	
3		24 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:77573-012-04	144 in 1 PACKAGE	07/11/2022	
4		43 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:77573-012-05	144 in 1 PACKAGE	07/11/2022	
5		78 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:77573-012-06	60 in 1 PACKAGE	07/11/2022	
6		130 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:77573-012-07	60 in 1 PACKAGE	07/11/2022	
7		181 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	07/10/2022	

Labeler - Jiangsu Aimeili Cosmetic Co.,Ltd. (543903077)

Registrant - Jiangsu Aimeili Cosmetic Co.,Ltd. (543903077)

Establishment

Name	Address	ID/FEI	Business Operations
Jiangsu Aimeili Cosmetic Co.,Ltd.		543903077	manufacture(77573-012)

Revised: 1/2024

Jiangsu Aimeili Cosmetic Co.,Ltd.