

FLUORIDE GEL- sodium fluoride paste
Yangzhou Tracey Daily Chemical Plastic Co., Ltd.

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.

Charm-Tex Fluoride Gel Toothpaste 73343-002

Active ingredients

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

Purpose

anticavity

Uses

helps protect against cavities.

Warnings

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

Keep out of reach of children.

Directions

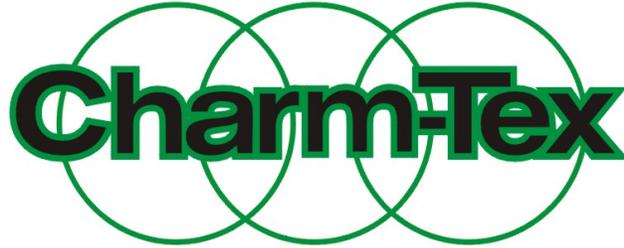
Adults and children 2years of age and older:Brush teeth thoroughly,preferably after each meal or at least twice a day,or as directed by a dentist or a physician.

Children 2-6 years:Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)

Children under 2 years:Ask a dentist or a physician.

INACTIVE INGREDIENT

Sorbitol,Silica,methyl Paraben Sodium,Propyl Paraben Sodium ,Flavour ,Sodium Saccharin,Treated Water,SCMC,Sodium Lauryl Sulfate



Net Wt. 1.5 oz.
43 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, SMC, 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

FLUORIDE GEL

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73343-002
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.22 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
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CARBOCYSTEINE LYSINE MONOHYDRATE (UNII: QA5ZP9OL3E)	
SORBITOL (UNII: 506T60A25R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
METHYL PARAOXON (UNII: UE1A2XL95H)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	
WATER (UNII: 059QF0KO0R)	
SODIUM SILICATE (UNII: IJF18F77L3)	
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73343-002-01	1 in 1 BOX	10/15/20 19	
1		43 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 not final	part356	10/14/20 19	

Labeler - Yangzhou Tracey Daily Chemical Plastic Co., Ltd. (560398069)

Registrant - Yangzhou Tracey Daily Chemical Plastic Co., Ltd. (560398069)

Establishment			
Name	Address	ID/FEI	Business Operations
Yangzhou Tracey Daily Chemical Plastic Co., Ltd.		560398069	manufacture(73343-002)

Revised: 10/2019

Yangzhou Tracey Daily Chemical Plastic Co., Ltd.