

CHARM TEX FLUORIDE- sodium fluoride paste
Yangzhou Hengyuan 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.

TOOTHPASTE DRUG FACTS

Active Ingredient

Sodium Fluoride 0.76%(0.1%w/v fluoride ion)

Purpose

Anticavity

Use

helps protect against cavities

Warning

Keep out of 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.

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:Use only a pea sized amount and supervise child's brushing and rinsing to minimize swallowing.

Children under 2:Ask dentist or physician

Inactive Ingredients

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

Keep out of reach of children under 6 years of age

Keep out of reach of children under 6 years of age

Charm-Tex

NET WT. 1.5 OZ
(43 GRAMS)

5.5mm

FLUORIDE TOOTHPASTE

6*2

DRUG FACTS		DIRECTIONS
Active ingredient: Sodium monofluorophosphate 0.76% (0.1% w/v fluoride ion)	PurposeAnticavity	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, Calcium Carbonate, Methyl Paraben Sodium, Propyl Paraben Sodium, Flavour, Sodium Saccharin, Treated water, SCMC, Sodium Lauryl Sulfate.		Children under 2 years: Ask a dentist or physician.
Product of china, Exclusive Distributor: Charm-Tex, Inc. USA, WWW.CHARM-TEX.COM		

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

Mfg. Date & Batch No. on crimp

Expiry: 2 years from the date of Mfg.

2mm

CHARM TEX FLUORIDE

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51289-200
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.76 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Sorbitol (UNII: 506T60A25R)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN SODIUM (UNII: 625NNB0G9N)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51289-200-01	17 g in 1 TUBE		
2	NDC:51289-200-02	24 g in 1 TUBE		
3	NDC:51289-200-03	35 g in 1 TUBE		
4	NDC:51289-200-04	43 g in 1 TUBE		
5	NDC:51289-200-05	50 g in 1 TUBE		
6	NDC:51289-200-06	70 g in 1 TUBE		
7	NDC:51289-200-07	78 g in 1 TUBE		
8	NDC:51289-200-08	90 g in 1 TUBE		
9	NDC:51289-200-09	100 g in 1 TUBE		
10	NDC:51289-200-10	120 g in 1 TUBE		
11	NDC:51289-200-11	130 g in 1 TUBE		
12	NDC:51289-200-12	150 g in 1 TUBE		
13	NDC:51289-200-13	180 g in 1 TUBE		
14	NDC:51289-200-14	3 g in 1 TUBE		
15	NDC:51289-200-15	5 g in 1 TUBE		
16	NDC:51289-200-16	10 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/10/2013	

Labeler - Yangzhou Hengyuan Daily Chemical Plastic Co., Ltd. (527127383)

Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou Hengyuan Daily Chemical Plastic Co., Ltd.		527127383	manufacture(51289-200)

Revised: 7/2013

Yangzhou Hengyuan Daily Chemical Plastic Co., Ltd.