

CHARM TEX FLUORIDE- sodium fluoride paste
Yangzhou Hongshengding Chemical 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, SMC,

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



Net Wt. 2.75 oz.
78 Grams

FLUORIDE TOOTHPASTE

3mm
2*8mm

DRUG FACTS		DIRECTIONS
Active ingredient:	Purpose	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.
Sodium monofluorophosphate 0.76% (0.1% w/v fluoride ion)Anticavity	
Use: helps protect against cavities.		Children 2 to 6 years: Use only a pea sized amount and supervise child's brushing and rinsing to minimize swallowing.
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.		
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		

3*8mm 4mm

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

Mfg. Date & Batch No. on crimp

Expiry: 2 years from the date of Mfg.

CHARM TEX FLUORIDE

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71035-200
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: EU2PSPOG0W)	
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:71035-200-01	17 g in 1 TUBE; Type 0: Not a Combination Product	10/20/2016	
2	NDC:71035-200-02	24 g in 1 TUBE; Type 0: Not a Combination Product	10/20/2016	
3	NDC:71035-200-03	35 g in 1 TUBE; Type 0: Not a Combination Product	10/20/2016	
4	NDC:71035-200-04	43 g in 1 TUBE; Type 0: Not a Combination Product	10/20/2016	
5	NDC:71035-200-05	50 g in 1 TUBE; Type 0: Not a Combination Product	10/20/2016	
6	NDC:71035-200-06	70 g in 1 TUBE; Type 0: Not a Combination Product	10/20/2016	
7	NDC:71035-200-07	78 g in 1 TUBE; Type 0: Not a Combination Product	10/20/2016	
8	NDC:71035-200-08	90 g in 1 TUBE; Type 0: Not a Combination Product	10/20/2016	
9	NDC:71035-200-09	100 g in 1 TUBE; Type 0: Not a Combination Product	10/20/2016	
10	NDC:71035-200-10	120 g in 1 TUBE; Type 0: Not a Combination Product	10/20/2016	
11	NDC:71035-200-11	130 g in 1 TUBE; Type 0: Not a Combination Product	10/20/2016	
12	NDC:71035-200-12	150 g in 1 TUBE; Type 0: Not a Combination Product	10/20/2016	
13	NDC:71035-200-13	180 g in 1 TUBE; Type 0: Not a Combination Product	10/20/2016	
14	NDC:71035-200-14	3 g in 1 TUBE; Type 0: Not a Combination Product	10/20/2016	
15	NDC:71035-200-15	5 g in 1 TUBE; Type 0: Not a Combination Product	10/20/2016	
16	NDC:71035-200-16	10 g in 1 TUBE; Type 0: Not a Combination Product	10/20/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/20/2016	

Labeler - Yangzhou Hongshengding Chemical Co.,Ltd. (543774755)

Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou Hongshengding Chemical Co.,Ltd.		543774755	manufacture(71035-200)

Revised: 1/2018

Yangzhou Hongshengding Chemical Co.,Ltd.