

**FLUORIDE GEL- 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.*

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**Charm-Tex Fluoride Gel Toothpaste**

**Active ingredients**

Sodium Fluoride 0.22%(0.15 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



Product of China, Exclusive Distributor: Charm-Tex, Inc. USA, WWW.CHARM-TEX.COM  
 N.C.No.: DD/COS/DD/C/340 Mfg. Date & Batch No. on crimp Expiry: 2 years from the date of Mfg.



Net Wt. 0.85 oz.  
24 Grams

## FLUORIDE GEL TOOTHPASTE

DRUG FACTS		DIRECTIONS
<b>Active ingredient:</b> Sodium Fluoride 0.22% (0.1% w/v fluoride ion)	<b>Purpose</b> Anticavity	<b>Adults and children 6 years of age and older:</b> brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or a physician.
<b>Use:</b> helps protect against cavities.		
<b>Warning:</b> 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.		<b>Children 2 to 6 years:</b> Use only a pea sized amount and supervise child's brushing and rinsing to minimize swallowing.
<b>Inactive ingredient:</b> Sorbitol, Silica, Methyl Paraben Sodium, Propyl Paraben Sodium, Flavour, Sodium Saccharin, Treated water, SCMC, Sodium Lauryl Sulfate		<b>Children under 2 years:</b> Ask a dentist or physician.
Product of China, Exclusive Distributor: Charm-Tex, Inc. USA, WWW.CHARM-TEX.COM		
N.C.No.: DD/COS/DD/C/340	Mfg. Date & Batch No. on crimp	Expiry: 2 years from the date of Mfg.

EPL



Net Wt. 1.5 oz.  
43 Grams

## FLUORIDE GEL TOOTHPASTE

DRUG FACTS		DIRECTIONS
<b>Active ingredient:</b> Sodium Fluoride 0.22% (0.1% w/v fluoride ion)	<b>Purpose</b> Anticavity	<b>Adults and children 6 years of age and older:</b> brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or a physician.
<b>Use:</b> helps protect against cavities.		
<b>Warning:</b> 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.		<b>Children 2 to 6 years:</b> Use only a pea sized amount and supervise child's brushing and rinsing to minimize swallowing.
<b>Inactive ingredient:</b> Sorbitol, Silica, Methyl Paraben Sodium, Propyl Paraben Sodium, Flavour, Sodium Saccharin, Treated water, SCMC, Sodium Lauryl Sulfate		<b>Children under 2 years:</b> Ask a dentist or physician.
Product of China, Exclusive Distributor: Charm-Tex, Inc. USA, WWW.CHARM-TEX.COM		
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:71035-400
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
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: JF18F77L3)	
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71035-400-01	720 in 1 BOX	05/25/2016	
1		17 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:71035-400-02	720 in 1 BOX	05/25/2016	
2		24 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:71035-400-03	144 in 1 BOX	03/07/2016	
3		43 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:71035-400-04	1000 in 1 BOX	05/01/2015	
4		0.22 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:71035-400-05	1000 in 1 BOX	05/01/2015	
5		7 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	05/01/2015	

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

Name	Address	ID/FEI	Business Operations
Yangzhou Hongshengding Chemical Co.,Ltd.		543774755	manufacture(71035-400)