FLUORIDE GEL- 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.

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.

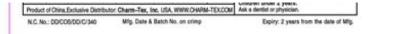
Children 2-6 years:Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)

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









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

Mfg. Date & Batch No. on crimp

FLUORIDE GEL

sodium fluoride paste

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51289-400
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

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: IJF18F77L3)	
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	

Packaging

# Item Code	Deckage Deceription	Marketing Start Date	Maxbating End Data
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:51289-400-01	720 in 1 BOX	05/25/2016	
1	17 g in 1 TUBE; Type 0: Not a Combination Product		
2 NDC:51289-400-02	720 in 1 BOX	05/25/2016	
2	24 g in 1 TUBE; Type 0: Not a Combination Product		
3 NDC:51289-400-03	144 in 1 BOX	0 3/0 7/20 16	
3	43 g in 1 TUBE; Type 0: Not a Combination Product		
4 NDC:51289-400-04	1000 in 1 BOX	0 5/0 1/20 15	
4	0.22 g in 1 TUBE; Type 0: Not a Combination Product		
5 NDC:51289-400-05	1000 in 1 BOX	0 5/0 1/20 15	
5	7 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Monograph Citation	Marketing Start Date	Marketing End Date	
(0 5/0 1/20 15		
	Monograph Citation	Marketing Start Date 05/01/2015	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou Hengyuan Daily Chemical Plastic Co., Ltd.		527127383	manufacture(51289-400)