

TOOTHPOWDER- sodium fluoride powder
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.

Charm-TEX toothpowder

Active ingredients

Sodium Fluoride 0.24%(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 accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Keep out of reach of children.

Directions

Adults and children 2 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 2-6 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

calcium carbonate, silica, mint flavour, sodium lauryl sulfate, sodium benzoate

4



Toothpowder, 2 oz. (by volume)

Active Ingredient:

.024% Sodium fluoride

MADE IN CHINA

3

DRUG FACTS	DIRECTIONS
Active ingredient: Purpose Sodium Fluoride 0.24% (0.1% w/v fluoride ion) ----- Antioavity	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 : Calcium carbonate ,Silica,Mint flavour, Sodium lauryl sulfate, Sodium Benzoate.	
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 & Bath No.: 20190901

Expiry: 2 years from the date of Mfg.

TOOTHPOWDER

sodium fluoride powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71035-500
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.24 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SODIUM SILICATE (UNII: IJF18F77L3)	
MINT (UNII: FV98Z8G1TP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71035-500-03	250 in 1 CARTON	09/09/2016	
1		85 g in 1 BAG; Type 0: Not a Combination Product		
2	NDC:71035-500-02	250 in 1 CARTON	09/09/2016	
2		57 g in 1 BAG; Type 0: Not a Combination Product		
3	NDC:71035-500-01	250 in 1 CARTON	09/09/2016	
3		28 g in 1 BAG; 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	09/04/2016	

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(71035-500)

Revised: 1/2018

Yangzhou Hongshengding Chemical Co.,Ltd.