

WESTERN DENTAL- 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.

Active ingredients

SODIUM MONOFLUOROPHOSPHATE 0.76%

Purpose

anticavity toothpaste

Uses

Aids in the prevention of dental 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 right away.

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 doctor.

Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing), supervise children as necessary until capable of using without supervision.Children under 2 years of age:consult a dentist or doctor.

INACTIVE INGREDIENT

calcium carbonate,CarboxyMethyl Cellulose ,glycerin,hydrated silica,purified water,Sodium Benzoate,Sodium Lauryl Sulfate,Sodium Saccharin,Sorbitol,Tetrasodium Diphosphate

Western Dental[®]

Mint Flavor

888-60-DENTAL

1 OZ

Drug Facts		Drug Facts (continued)
Active ingredient Sodium Monofluorophosphate (0.76%).....	Purpose Anticavity	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 doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor.
Uses Aids in the prevention of dental cavities.		Inactive Ingredients Calcium Carbonate, Carboxy Methyl Cellulose, Flavour, Glycerin, Hydrated Silica, Purified Water, Sodium Benzoate, Sodium Lauryl Sulphate, Sodium Saccharin, Sorbitol, Tetrasodium Diphosphate.
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 right away.		

WESTERN DENTAL

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:710 35-800
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
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	

CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
PHYTONADIOL TETRASODIUM DIPHOSPHATE (UNII: X952T8E4RN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71035-800-01	6 in 1 CARTON	02/11/2016	
1		24 in 1 BOX		
1		28.35 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	02/11/2016	

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(71035-800)

Revised: 6/2017

Yangzhou Hongshengding Chemical Co.,Ltd.