

RAIN BREEZE TOOTHPASTE - 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.

TOOTHPASTE DRUG FACTS

Active Ingredient

Sodium Fluoride 0.22%(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

Rain Breeze™

FLUORIDE *Gel* TOOTHPASTE NET WT. 0.60 oz (17g)

DRUG FACTS		DRUG FACTS(continued)	
Active ingredient: Sodium Fluoride 0.22% (0.1%w/v fluoride ion)	Purpose Anticavity	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.
Use: helps protect against cavities.		Children 2 to 6	use only a pea sized amount and supervise child's brushing and rinsing to minimize swallowing
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 contraol center immediately.		Children under 2	Ask dentist or physician.
		Inactive Ingredients: Sorbitol, Silica, Methyl Paraben Sodium, Propyl Paraben Sodium, Sodium Saccharin, Flavour, Treated water, SCMC, Sodium Lauryl Sulfate.	

Infinity Hospitality Group, Corona, Ca, 92877

Made in PRC.

Mfg Date

Exp. Date: 3 years from date of mfg.



RAIN BREEZE TOOTHPASTE

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51289-100
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.22 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Sorbitol (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN SODIUM (UNII: 625NNB0G9N)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0K00R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	

Sodium Lauryl Sulfate (UNI: 368GB5141J)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51289-100-01	17 g in 1 TUBE		
2	NDC:51289-100-02	24 g in 1 TUBE		
3	NDC:51289-100-03	35 g in 1 TUBE		
4	NDC:51289-100-04	43 g in 1 TUBE		
5	NDC:51289-100-05	50 g in 1 TUBE		
6	NDC:51289-100-06	70 g in 1 TUBE		
7	NDC:51289-100-07	78 g in 1 TUBE		
8	NDC:51289-100-08	90 g in 1 TUBE		
9	NDC:51289-100-09	100 g in 1 TUBE		
10	NDC:51289-100-10	120 g in 1 TUBE		
11	NDC:51289-100-11	130 g in 1 TUBE		
12	NDC:51289-100-12	150 g in 1 TUBE		
13	NDC:51289-100-13	180 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/21/2010	

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

Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou Hengyuan Daily Chemical Plastic Co., Ltd.		527127383	manufacture

Revised: 8/2010

Yangzhou Hengyuan Daily Chemical Plastic Co., Ltd.