

MINTBLAST ANTI CAVITY FLUORIDE- 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.

Anti Cavity Fluoride Toothpaste

Active ingredients

Sodium Fluoride 0.243%(0.15% w/v Fluoride ion)

Purpose

anticavity

Uses

Aids in the prevention of cavities.

Warnings

Keep out of the reach of children under 6 years of age.if you accidentally swallow more than used for brushing.seek professional assistance 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

Glycerine,Sorbitol,Saccharin Sodium,Sodium benzoate,Sodium Carboxy Methyl Cellulose,Xanthan Gum,Sodium Fluoride,Treated Water,Silica,Sodium Lauryl Sulfate,Titanium Dioxide,Flavor,CI42090



Inactive Ingredients: Glycerine, Sorbitol, Saccharin Sodium, Sodium Benzoate, Sodium Carboxy Methyl Cellulose, Xanthan Gum, Sodium Fluoride, Treated Water, Silica, Sodium Lauryl Sulfate, Titanium Dioxide, Flavor, CI42090

Warnings: keep out of the reach of children under 6 years of age. If you accidentally swallow more than used for brushing, seek professional assistance or contact a Poison Control Center immediately.

Drug Facts:	Directions:	
Active Ingredient Sodium Fluoride...0.243% (0.15% w/v Fluoride ion)	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.
Purpose: Anticavity	Children 2 to 6 years	Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing).
Use: Aids in the prevention of cavities	Children under 2 years	Ask a dentist or a physician.
Distributed by: PLAK SMACKER ® Algonquin, IL 60102 www.plaksmacker.com 800-558-6684 Made in China Batch No., Pkd. & Expiration on crimp.		

MINTBLAST ANTI CAVITY FLUORIDE

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71035-300
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.243 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
DISODIUM CARBOXYMETHYLARSONATE (UNII: T9HTL93NB7)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0K00R)	
SODIUM SILICATE (UNII: IJF18F77L3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71035-300-01	144 in 1 BOX	04/15/2016	
1		9.9 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:71035-300-02	72 in 1 BOX	04/15/2016	
2		9.9 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:71035-300-03	144 in 1 BOX	03/07/2016	
3		28.35 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:71035-300-04	72 in 1 BOX	03/07/2016	
4		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(71035-300)

Revised: 1/2018

Yangzhou Hongshengding Chemical Co.,Ltd.