

MINTBLAST ANTI CAVITY FLUORIDE- 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.

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:51289-300 |
| 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:51289-300-01 | 144 in 1 BOX | 04/15/2016 | |
| 1 | | 9.9 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:51289-300-02 | 72 in 1 BOX | 04/15/2016 | |
| 2 | | 9.9 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 3 | NDC:51289-300-03 | 144 in 1 BOX | 03/07/2016 | |
| 3 | | 28.35 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 4 | NDC:51289-300-04 | 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 | 03/07/2016 | |

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(51289-300) |

Revised: 4/2016

Yangzhou Hengyuan Daily Chemical Plastic Co.,Ltd