MINTBLAST- sodium fluoride paste YOUNG PS ACQUISITION, LLC

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.

MINTBLAST ANTICAVITY FLUORIDE TOOTH PASTE

Active ingredient

Sodium Fluoride - 0.243% (0.13% w/v Fluoride ion)

Purpose

Anticavity

Use

Aids in the prevention of cavities.

Directions:

- Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or use as directed by a dentist or a physician.
- Children 2 to 6 years: Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing).
- Children under 2 year : Ask a dentist or physician .

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.

Inactive Ingredients

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

Mint Blast Product Label



MINTBLAST

sodium fluoride paste

P	ro	duct	Information
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:72326-8011

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

SODIUM FLUORIDE (UNII: 8 ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)

FLUORIDE ION

2.43 mg in 1 g

Ingredient Name Strength SORBITOL (UNII: 506T60A25R) SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) WATER (UNII: 059QF0KO0R) GLYCERIN (UNII: PDC6A3C0OX) SODIUM LAURYL SULFATE (UNII: 368GB5141J) TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) CARBO XYMETHYLCELLULO SE SODIUM (UNII: K679OBS311)

SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT (MINT)	Imprint Code	
Contains			

Packaging					
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:72326-8011-1	28 g in 1 TUBE; Type 0: Not a Combination Product	05/26/2018		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	05/26/2018		

Labeler - YOUNG PS ACQUISITION, LLC (119620784)

Establishment					
Name	Address	ID/FEI	Business Operations		
Yangzhou Hongshengding Chemical Co.,Ltd.		543774755	manufacture (72326-8011)		

Revised: 5/2018 YOUNG PS ACQUISITION, LLC