

**PLAK SMACKER MINT BLAST- sodium fluoride paste
LMZ**

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.

Mint Blast Toothpaste

Active Ingredients

Sodium Fluoride 0.243% (equivalent to 0.13% w/v fluoride ion)

Purpose

Anti-cavity

Uses

Aids in the prevention of cavities

Warnings

If you accidentally swallow more than used for brushing, get medical help or contact a Poison Control Center immediately.

Keep out of reach of children under 6 years of age.

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 a physician.

Children 2 to 6 years: To minimize swallowing use a pea sized amount. Supervise children's brushing until good habits are established.

Children under 2 years: Ask a dentist or a physician.

Inactive Ingredients

Sorbitol, Silica, Water, PEG-8, Sodium lauryl sulfate, Flavor, Titanium dioxide, Cellulose gum, Trisodium phosphate, Sodium saccharin, Xanthan gum, Benzyl alcohol, Xylitol, CI 42090

Principal Display Panel

28 g NDC: 71775-080-01



Inactive Ingredients: Sorbitol, Silica, Water, PEG-8, Sodium Lauryl Sulfate, Flavor, Titanium Dioxide, Cellulose Gum, Trisodium Phosphate, Sodium Saccharin, Xanthan Gum, Benzyl Alcohol, Xylitol, Sodium Fluoride, CI 42090.

Warnings: Keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, get medical help or contact a Poison Control Center immediately.

Drug Facts:	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 a physician.
Active Ingredient Sodium Fluoride...0.243% (0.13% w/v Fluoride only)	Children 2 to 6 years	To minimize swallowing use a pea sized amount. Supervise children's brushing until good habits are established.
Purpose: Anti-Cavity	Children under 2 years	Ask a dentist or a physician.
Use: Aids in the prevention of cavities	Distributed By: Young Innovations, Inc., 2260 Wendt Street, Algonquin, IL 60102 USA Toll Free (800) 558-6684 • www.youngspecialties.com • REF 400022 Rev. B • Made in China	

PLAK SMACKER MINT BLAST

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71775-080
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	130 mg in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS (UNII: SX01TZO3QZ)	

CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71775-080-01	28 g in 1 TUBE; Type 0: Not a Combination Product	03/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/18/2021	

Labeler - LMZ (654623156)

Establishment

Name	Address	ID/FEI	Business Operations
LMZ		654623156	manufacture(71775-080)

Revised: 3/2021

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