

ORAZEN- sodium monofluorophosphate paste

Orazen Inc

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.

Orazen Kids Anticavity Toothpaste

Active Ingredient

Sodium Monofluorophosphate 0.76%

Purpose

Anti-Cavity Toothpaste

Use: Helps prevent against cavities

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

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

Directions: adults and children 2yrs. and older: brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist. To minimize swallowing use a pea sized amount in children under 6. Supervise children's brushing until good habits are established. Children under 2 yrs.: ask a dentist

Inactive Ingredients: Sorbitol, Hydrated Silica, Water, Peg-8, Sodium Lauryl Sulfate, Flavor, Cellulose Gum, Sodium Saccharin, Trisodium Phosphate, Mica, Sodium Benzoate, CI 73015

Orazen

Orazen Inc

Somerset, NJ 08873

Questions 888-349-7897

Info@orazeninc.com

Made in China/Hecho en China

Fabrique en Chine

Ora-Zen Anticavity Toothpaste

Bubblegum



ANTICAVITY FLUORIDE TOOTHPASTE



NET WT
1 OZ (28g)

Drug Facts / Instructions		Drug Facts (continued)
Active Ingredient Sodium monofluorophosphate 0.76%.....	Purpose Anti-Cavity Toothpaste	twice a day or as directed by a dentist. To minimize swallowing use a pea sized amount in children under 6. Supervise children's brushing until good habits are established. • Children under 2 years: ask a dentist
Use Helps prevent against cavities		Inactive Ingredients Sorbitol, Hydrated Silica, Water, PEG-8, Sodium Lauryl Sulfate, Flavor, Cellulose Gum, Sodium Saccharin, Trisodium Phosphate, Mica, Sodium Benzoate, CI 73015
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.		
Directions • Adults and children 2 years of age and older: Brush teeth thoroughly after meals or at least.		CAUTION/CHOKING HAZARD: This product is not a toy and should always be used with adult supervision. Not intended for children under 2 years of age.

Distributed by: Orazen Inc.
Somerset, NJ 08873

Questions 888-349-7897
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MADE IN CHINA

ORAZEN

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71927-102
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
MICA (UNII: V8A1AW0880)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM PHOSPHIDE (UNII: A360RQX9W2)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71927-102-01	1 in 1 POUCH	04/01/2023	
1		28 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	04/01/2023	

Labeler - Orazen Inc (080916640)

Registrant - Orazen Inc (080916640)

Establishment

Name	Address	ID/FEI	Business Operations
YANGZHOU SION COMMODITY CO		546806042	manufacture(71927-102)