

IODENT TOOTH- sodium monofluorophosphate paste
Zhaoqing Longda Biotechnology 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.

72129 001

Active Ingredient

sodium monofluorophosphate 0.76%

Purpose

Anticavity

Use

Regular brushing with fluoride toothpaste helps protect teeth and roots against cavities

Warning

Keep out of reach under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Adults and children 2 years and older brush teeth thoroughly, preferably after each meal or as least twice a day , or as directly by a dentist or doctor

Children under 6 years of age In good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision

Children under 2 years of age Consult a dentist or doctor

Inactive Ingredients

calcium carbonate , water, sorbitol , silica, polyethylene glycol 400, sodium laury alcohol, sodium carboxymethyl cellulose, flavor, sodium saccharin, methylparaben, propylparaben , sodium hydroxide

Keep out of reach of children under 6 years of age

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IODENT TOOTH

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72129-001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.76 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	

SODIUM SILICATE (UNII: IJF18F77L3)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYPERONE (UNII: HG22108KQK)	
SODIUM CARBOXYMETHYL .BETA.-GLUCAN (DS 0.65-0.85) (UNII: 2YGO1190AP)	
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72129-001-01	24 in 1 BOX	02/02/2018	
1		6 in 1 PACKAGE		
1		181 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 final	part355	02/02/2018	

Labeler - Zhaoqing Longda Biotechnology Co., Ltd. (546452557)

Establishment

Name	Address	ID/FEI	Business Operations
Zhaoqing Longda Biotechnology Co., Ltd.		546452557	manufacture(72129-001)

Revised: 2/2022

Zhaoqing Longda Biotechnology Co., Ltd.