

**WHITE-GLO 2IN1 WITH MOUTHWASH- sodium monofluorophosphate paste
HUAIAN ZONGHENG BIO-TECH 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.

Active Ingredient

sodium monofluorophosphate 0.76%

Purpose

Anticavitytoothpaste

Use

helps protect against cavities

Warning

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

If more than used for brushing is accidentally swallowed get medical help or contact a poison control center right away.

Directions

Adults and children 6 years of age and older:brush teeth thoroughly, after meals or at least twice a day or use as directed by a dentist.

do not swallow

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

Inactive Ingredients

Calcium Carbonate,Aqua,Glycerin,denature alcohol(2.5%),Sorbitol,Silica,Aroma,Sodium Lauryl Sulphate,Carboxymethyl Hydroxyethyl cellulose,Chondrus Crispus,CI77891(Titanium Dioxide),Sodium saccharin,rose canina fruit oil

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WHITE-GLO 2IN1 WITH MOUTHWASH

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71167-002
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
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0K00R)	

GLYCERIN (UNII: PDC6A3C0OX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SORBITOL (UNII: 506T60A25R)	
SODIUM SILICATE (UNII: JF18F77L3)	
SODIUM LAURYL SULFATE (UNII: 368GB514J)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	
ROSA CANINA FLOWER OIL (UNII: DUY7M48IIT)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71167-002-01	24 in 1 BOX	07/10/2016	
1		150 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:71167-002-02	48 in 1 BOX	07/10/2016	
2		150 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	07/10/2016	

Labeler - HUIAN ZONGHENG BIO-TECH CO., LTD (527152733)

Establishment

Name	Address	ID/FEI	Business Operations
HUIAN ZONGHENG BIO-TECH CO., LTD		527152733	manufacture(71167-002)

Revised: 3/2017

HUIAN ZONGHENG BIO-TECH CO., LTD