

ADOPTAPLATOON- 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 burshing ntil good habits are established

children under 2 years ask a dentist

Inactive Ingredients

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

Keep out of reach of children under 6 years of age

Keep out of reach of children under 6 years of age

AdoptaPlatoon®

AdoptaPlatoon.org

DRUG FACTS		DRUG FACTS (continued)
Active ingredient: Sodium Monofluorophosphate 0.76%.....Anticavitytoothpaste	Purpose	Directions: <ul style="list-style-type: none"> ● Adults and children 2 years&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
Use: helps protect against cavities		Inactive ingredients: Calcium Carbonate, Aqua(Water), Glycerin, Sorbitol, Silica, Aroma(Flavor), Sodium Lauryl Sulphate, Carboxymethyl Hydroxyethylcellulose, Chondrus Crispus (Carrageenan), C177891 (Titanium Dioxide), Sodium Saccharin, Rosa CaninaFruit Oil.
Warnings: 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.		

ADOPTAPLATOON

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71167-001
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
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SORBITOL (UNII: 506T60A25R)	
SODIUM SILICATE (UNII: UJF18F77L3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	

POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)

ROSA CANINA FLOWER OIL (UNII: DUY7M48IIT)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71167-001-01	10 g in 1 TUBE; Type 0: Not a Combination Product	01/13/2017	
2	NDC:71167-001-02	25 g in 1 TUBE; Type 0: Not a Combination Product	01/13/2017	
3	NDC:71167-001-03	30 g in 1 TUBE; Type 0: Not a Combination Product	01/13/2017	
4	NDC:71167-001-04	24 in 1 BOX	07/10/2016	
4		150 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:71167-001-05	48 in 1 BOX	07/10/2016	
5		150 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:71167-001-06	48 in 1 BOX	07/10/2016	
6		150 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:71167-001-07	288 in 1 BOX	07/10/2016	
7		50 g in 1 TUBE; Type 0: Not a Combination Product		
8	NDC:71167-001-08	144 in 1 BOX	07/10/2016	
8		60 g in 1 TUBE; Type 0: Not a Combination Product		
9	NDC:71167-001-09	144 in 1 BOX	07/10/2016	
9		70 g in 1 TUBE; Type 0: Not a Combination Product		
10	NDC:71167-001-10	72 in 1 BOX	07/10/2016	
10		85 g in 1 TUBE; Type 0: Not a Combination Product		
11	NDC:71167-001-11	144 in 1 BOX	07/10/2016	
11		85 g in 1 TUBE; Type 0: Not a Combination Product		
12	NDC:71167-001-12	144 in 1 BOX	07/10/2016	
12		100 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(71167-001)

Revised: 1/2017

HUIAN ZONGHENG BIO-TECH CO., LTD