

GLO SCINECE ANTIOXIDANT- fluoride paste, dentifrice

GLO Science 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.

Drug Facts

Active ingredients

Active Ingredient: SODIUM MONOFLUOROPHOSPHATE 0.84% FLUORIDE ION

PURPOSE: ANTICAVITY

Use

- aids in the prevention of dental cavities

Uses

aids in the prevention of dental cavities

Keep out of reach of children

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 recommended by a dentist or doctor.

Children 2 to 6 years: Use a pea sized amount (to minimize swallowing), supervise until good brushing habits are established. Children under 2 years of age: Consult a dentist or doctor.

Inactive ingredients

Inactive ingredients:

Water, sorbitol, glycerin, hydrated silica, xylitol, titanium dioxide, Cocamidopropyl Betaine, Sodium Methyl Cocoyl Taurate, Flavor, Maltodextrin, Tocopheryl Acetate, Sodium Ascorbyl Phosphate, Vitis Vinifera (Grape) Seed Extract, Helianthus Annuus (Sunflower) Oil, Acacia Senegal Gum, Ubiquinone (Coenzyme Q10), White Cranberry Juice Concentrate, Stevia Rebaudiana Extract, Cellulose Gum, Xanthan Gum, Zinc Lactate, Folic Acid, Ammonium Glycyrrhizinate, Gelatin, Potassium Sorbate, Sodium Hydroxide, FDC Red 30

Customer Confirmation

Printing Instruction



cosmopak
www.cosmopak.com

PO#: _____
Name: _____
Code: _____
Spec: _____



Actual print height 134 mm

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. **Directions:** Adults and children 2 years of age and older: brush teeth thoroughly, after each meal or at least twice a day, or as directed by a dentist or doctor. **Children 2 to 6 years of age:** use only a pea-sized amount (to minimize swallowing) and supervise child's brushing until good habits are established. **Children under 2 years of age:** consult a dentist or doctor. **Inactive ingredients:** water, sorbitol, glycerin, hydrated silica, xylitol, titanium dioxide, polydimethylsiloxane, sodium methyl cocoyl taurate, flavor, malodestrol, tocopheryl acetate, sodium ascorbyl phosphate, Vitis Vinifera (grape) seed extract, Heliopsis scabra (sunflower) oil, acacia senegal gum, ubiquinol (coenzyme Q10), white cranberry juice concentrate, stevia rebaudiana extract, cellulose gum, xanthan gum, zinc lactate, lactic acid, ammonium glycyrrhizate, gelatin, potassium sorbate, sodium hydroxide, FD&C red 50. **Questions or comments?** Call toll free 1-855-456-5976. **Distributed by:** GLO Science, Inc. New York, NY 10017. www.gloscience.com.

Color	1	2	3	4	5	6
PMS						

Designer :

Reviewed :

Approval :

190
180
170
160
150
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0 (mm)



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 immediately.

GLO SCIENCE ANTIOXIDANT

fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49993-860
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM MONOFLUOROPHOSPHATE	0.84 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
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SORBITOL (UNII: 506T60A25R)
WATER (UNII: 059QF0KO0R)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ZINC LACTATE (UNII: 2GXR25858Y)
FOLIC ACID (UNII: 935E97BOY8)
CRANBERRY (UNII: 0MVO31Q3QS)
VITIS VINIFERA SEED (UNII: C34U15ICXA)
UBIDECARENONE (UNII: EJ27X76M46)
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
GLYCERIN (UNII: PDC6A3C0OX)
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)
HYDRATED SILICA (UNII: Y6O7T4G8P9)
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)
SUNFLOWER OIL (UNII: 3W1JG795YI)
GELATIN (UNII: 2G86QN327L)
ACACIA (UNII: 5C5403N26O)
XANTHAN GUM (UNII: TTV12P4NEE)

Product Characteristics

Color	red (red 30)	Score	
Shape		Size	
Flavor	MINT (Hagelin 623097 N&A Berry Mint Flavor O.S.)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49993-860-09	1 in 1 CARTON		
1	NDC:49993-860-02	141.7 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/01/2012	

Labeler - GLO Science Inc (961623019)