

PROFESSIONAL WHITENING SYSTEM WHITENING- sodium fluoride paste
AKG Innovations LLC

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.

PROFESSIONAL WHITENING SYSTEM WHITENING TOOTHPASTE with Fluoride

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Active Ingredient

SODIUM FLUORIDE 0.23%...

Purpose

Anticavity

Uses

Aids in the prevention of dental cavities.

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.

Directions

Supervise children as necessary until capable of using without supervision.

- Adults and children 6 years of age and older, brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician.
- Children under 12 years, instruct in good brushing and rinsing habits (to minimize swallowing).
- Children under 6 years, do not use unless directed by a dentist or physician.

Inactive Ingredients

WATER, SORBITOL, HYDRATED SILICA, GLYCERIN, XYLITOL, FLAVOR,
CELLULOSE GUM, SODIUM LAUROYL SARCOSINATE, SODIUM SACCHARIN,
CARRAGEENAN, TITANIUM DIOXIDE,
HYDROGEN PEROXIDE, MENTHOL, SALVADORA PERSICA BARK/ROOT EXTRACT.

Questions or comments:

Call Customer Service-toll free

1-855-333-2544 or visit www.arthurglosmandentalbeauty.com

PROFESSIONALWHITENING SYSTEM WHITENINGTOOTHPASTE with Fluoride 113.6 g
(62111-0213-2)

advanced dental

health +beauty

ARTHUR GLOSMAN DDS

Beverly Hills

PROFESSIONAL

WHITENING SYSTEM

WHITENING

TOOTHPASTE

with Fluoride

Net Wt. 4.2 oz. / 113.6 g

A refreshing, peppermint flavored toothpaste, formulated with Hydrogen Peroxide for a healthier looking, whiter smile, silica to help remove surface stains, menthol to cool and Salvadora Persica, also known as nature's tooth brush. When used in conjunction with twice daily flossing and rinsing with Whitening Mouth Wash this invigorating toothpaste helps promote good oral hygiene.

The Dr. Glosman Dental Beauty line contains dental products as well as skin treatments:

Professional Whitening System with Refills

Professional Whitening Pen

Whitening Toothpaste with Fluoride

Whitening Mouth Wash with Fluoride

Slim Sonic Tooth Brush

Moisturizing Lip Balm

Lip Enhancer Gloss

Lip Area Rescue Treatment

Important:

Read directions on
carton for proper use.

Distributed by:

AKG Innovations, LLC

450 N. Roxbury Drive

Suite 222

Beverly Hills, CA 90210

Made in USA #90215

Drug Facts

Active ingredient

SODIUM FLUORIDE 0.23%

Uses

■ Aids in the prevention of dental cavities

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.

Directions ■ Supervise children as necessary until capable of using without supervision. ■ Adults and children 6 years of age and older, brush teeth

Drug Facts (continued)

thoroughly, preferably after each meal, or at least twice a day, or as directed by a dentist or physician. ■ Children under 12 years, instruct in good brushing and rinsing habits (to minimize swallowing). ■ Children under 6 years, do not use unless directed by a dentist or physician.

Inactive ingredients: WATER, SORBOL, HYDRATED SILICA, Glycerin, XYLITOL FLAVOR, CELLULOSE GUM, SODIUM LAURYL SARCOSINATE, SODIUM SACCHARIN, CARBAMIDEMAN, TITANIUM DIOXIDE, HYDROGEN PEROXIDE, MENTHOL, SALVADORA PERSICA BARK/ROOT EXTRACT.

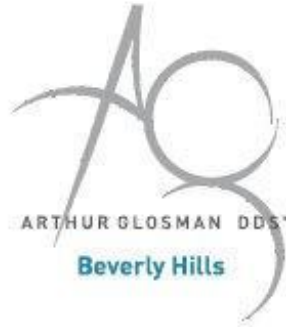
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The **Dr. Glosman Dental Beauty** line contains dental products as well as skin treatments:

- Professional Whitening System with Refills
- Professional Whitening Pen
- Whitening Toothpaste with Fluoride
- Whitening Mouth Wash with Fluoride
- Slim Sonic Tooth Brush
- Moisturizing Lip Balm
- Lip Enhancer Gloss
- Lip Area Rescue Treatment

A refreshing, peppermint flavored toothpaste, formulated with Hydrogen Peroxide for a healthier looking, whiter smile, silica to help remove surface stains, menthol to cool and *Salvadora Persica*, also known as nature's tooth brush. When used in conjunction with twice daily flossing and rinsing with Whitening Mouth Wash this invigorating toothpaste helps promote good oral hygiene.

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TOOTHPASTE

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Active ingredient Purpose

SODIUM FLUORIDE 0.23%... Anticavity

Use: Aids in the prevention of 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.

A refreshing, peppermint flavored toothpaste, formulated with Hydrogen Peroxide for a healthier looking, whiter smile.

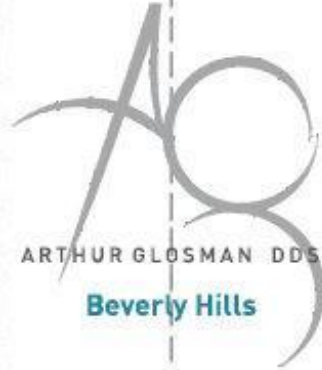
Directions: Adults and children 6 years of age and older brush teeth thoroughly at least twice a day, or as directed by a dentist or physician.

Important: Read directions on carton for proper use.

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PROFESSIONAL
WHITENING SYSTEM

WHITENING
TOOTHPASTE

with Fluoride

Net Wt. 4.2oz. / 113.6g

PROFESSIONAL WHITENING SYSTEM WHITENING

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62111-0213
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.23 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
SODIUM SARCOSINATE (UNII: 6EHN3PQL8Z)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
MENTHOL (UNII: L7T10EIP3A)	
SALVADORA PERSICA ROOT (UNII: 526M7ZU616)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62111-0213-2	1 in 1 PACKAGE		
1		113.6 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/14/2014	

Labeler - AKG Innovations LLC (056576137)

Establishment

Name	Address	ID/FEI	Business Operations
Wasatch Product Development LLC		962452533	manufacture(62111-0213)

Revised: 2/2014

AKG Innovations LLC