

PROFESSIONAL WHITENING SYSTEM WHITENING MOUTH WASH- sodium fluoride mouthwash
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 MOUTH WASH

Drug Facts

Active ingredient

Sodium fluoride 0.02%

Purpose

Anticavity

Uses

■ Aids in the prevention of dental cavities

Warnings

Stop use and ask a dentist

if oral irritation or tooth sensitivity occurs

Keep out of reach of children.

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 12 years of age or older:
 - use twice daily after brushing your teeth with a toothpaste
 - vigorously swish 10 ml (2 teaspoonfuls) of rinse between your teeth for 1 minute and then spit out
 - do not swallow the rinse
 - do not eat or drink for 30 minutes after rinsing
 - supervise children as necessary until capable of using without supervision
 - Children under 12 years of age consult a dentist or doctor

Inactive ingredients

WATER, XYLITOL,

GLYCERIN, SORBITOL, PEG-40 HYDROGENATED
CASTOR OIL, FLAVOR, MENTHOL, HYDROGEN PEROXIDE,
POTASSIUM SORBATE, SODIUM BENZOATE, SODIUM
SACCHARIN, ASCORBIC ACID, SALVADORA PERSICA
BARK/ROOT EXTRACT, ZINC LACTATE.

Other information

■ Store at room temperature.

Questions?

Call Customer Service-toll-free

1.855.333.2544 or visit

www.arthurglosmandentalbeauty.com

PROFESSIONAL WHITENING SYSTEM WHITENING MOUTH WASH with Fluoride (62111-0212-4)

advanced dental

health + beauty

Arthur Glosman DDS

Beverly Hills

PROFESSIONAL

WHITENING SYSTEM

WHITENING

MOUTH WASH

with Fluoride

7.4 fl. oz. / 220 mL

| Active ingredient | Purpose |
|-------------------|---------|
|-------------------|---------|

| | |
|-----------------------|------------|
| SODIUM FLUORIDE 0.02% | Anticavity |
|-----------------------|------------|

With Hydrogen Peroxide to help whiten

teeth; a refreshing mint flavor; menthol

for a cooling sensation; and Salvadora

Persica also known as nature's tooth

brush.

Important:

■ Read directions on carton for proper
use.

Directions for use:

■ Use twice daily after brushing, with

Dr. Glosman's WHITENING TOOTHPASTE

■vigorously swish 10 ml, (2 teaspoons)

between the teeth for 1 minute and

then spit out.

■Do not swallow.

Distributed by:

AKG Innovations, LLC

450 N. Roxbury Drive

Suite 222

Beverly Hills, CA 90210

Made in USA

A refreshing, mint flavored wash, specially formulated with Hydrogen Peroxide for a healthier looking, whiter smile, menthol to cool the mouth and Salvadora Persica, also known as nature's tooth brush. When used in conjunction with twice daily, regular brushing and flossing, this refreshing wash 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

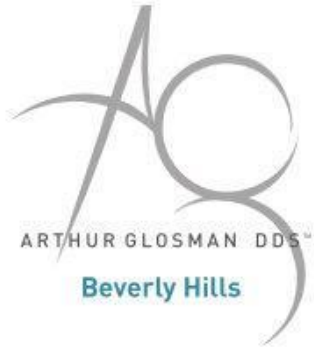
Slim Sonic Tooth Brush

Moisturizing Lip Balm

Lip Enhancer Gloss

Lip Area Rescue Treatment

advanced dental
health+beauty



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MOUTH WASH

with Fluoride

7.4 fl. oz. / 220 mL

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WHITENING
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R SODIUM FLUORIDE 0.02% } Anticavity

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#90218

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Other information

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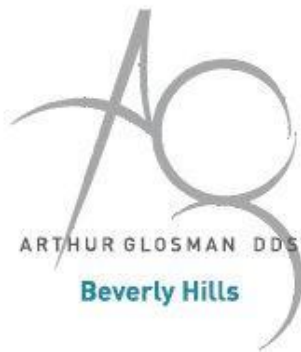
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sodium fluoride mouthwash

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62111-0212 |
| Route of Administration | oral | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | .2 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SORBITOL (UNII: 506T60A25R) | |
| CASTOR OIL (UNII: D5340Y2I9G) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) | |
| SALVADORA PERSICA ROOT (UNII: 526M7ZU616) | |
| ZINC LACTATE (UNII: 2GXR25858Y) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:62111-0212-4 | 220 mL in 1 BOTTLE | | |

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(62111-0212) |

Revised: 2/2014

AKG Innovations LLC