CLOSYS FLUORIDE RINSE- sodium fluoride rinse
Rowpar Pharmaceuticals, Inc.
Reference Label Set Id: e164f877-3163-4c16-afae-ff83efb079d9

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.

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CloSYS® Silver ALCOHOL-FREE Fluoride Rinse

Drug Facts

Active ingredient
Sodium fluoride 0.05% (0.02% w/v fluoride ion)

Purpose
Anticavity

Use: • Aids in prevention of dental cavities

Warning

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 6 years of age and older:
• use once a day after brushing your teeth with a toothpaste
• remove cap
• pour out and 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
• instruct children under 12 years of age in good rinsing habits (to minimize swallowing)
• supervise children as necessary until capable of using without supervision

Children under 6 years of age: consult a dentist or doctor

Inactive ingredients
water, stabilized chlorine dioxide, trisodium phosphate, citric acid, peppermint flavor, sucralose

Other Information
• do not use if safety seal is broken or missing
Questions or comments? Call 1-800-643-3337

**Best when used with cloSYS Toothpaste 2X a day**

*Non-Irritating: for Sensitive Mouths*

- *Alcohol-Free*       - *Sulfate-Free*
- *Non-Burning*      - *Non-Irritating*

A Cleaner Mouth. A Healthier You.®

**Strengthens Weakened Enamel**

**Gentle MINT FLAVOR with Fluoride**

*The cloSYS complete Oral Health System®*

Use CloSYS Silver Fluoride Rinse together with CloSYS Fluoride Toothpaste twice a day as directed. Visit CloSYS.com to learn more and discover “A Cleaner Mouth. A Healthier You.®”

**Oral Care as We Age**

**Specially Formulated for the changing oral care needs of Adults 55+**

As we age we become more vulnerable to developing chronic diseases. Research points to possible links between adult gum conditions and various diseases like; heart disease, diabetes, stroke, pneumonia, osteoporosis, and more. CloSYS, while not a prevention or cure for these diseases, helps fight the challenges of adult oral conditions.

**CloSYS Silver™ helps with:**

- Mild to moderate sensitivity & dry mouth
- Strengthening enamel
- Anticavity protection
- Dentist recommended to help relieve discomfort due to canker sores or chemotherapy sores

**Your Changing Oral Health**

- Increased sensitivity may happen because as we age the enamel on your teeth can suffer from acid erosion, making your mouth more sensitive to the food and drink we consume.
- Dry mouth is a common side effect of many prescription and over the counter medications.
- Painful mouth sores can occur due to sensitivity to sulfates and as side effects from medications including some chemotherapy drugs.

**How Does cloSYS Silver Fluoride Rinse Work?**

CloSYS recognizes the changing needs of adults and has developed CloSYS Silver specifically to help keep your mouth healthy at any age. CloSYS Silver uses a patented Cloralstan formula naturally activated by the amino acids in your saliva. Once activated CloSYS helps protect your teeth, with fluoride added, to aid in remineralizing enamel without the discomfort often found in other oral care products.

**The CloSYS 100% Satisfaction Guarantee**

It’s simple: If you’re not absolutely satisfied for any reason with CloSYS Oral Health Products we’ll refund your purchase in full.

*Use of stabilized chlorine dioxide system is protected under patent # 8,926,951 and other U.S. and foreign patents*

#1 Best Seller Recommended by Dental Professionals

FOR YOUR PROTECTION, this bottle has been sealed with an inner cap. DO NOT USE if the seal is broken. For maximum effectiveness, store at room temperature.
Factory sealed for your protection. Do not use if seal is broken.

IMPORTANT: Read directions for proper use

Please Note: Do not use if the tamper seal is loose, missing, or broken. If spilled on fabric wash out immediately to avoid discoloration of certain fabrics. Although CloSYS is completely safe, swallowing is not recommended.

DISTRIBUTED BY:
Rowpar Pharmaceuticals, Inc.
Scottsdale, AZ 85260
1 (800) 643-3337
closys.com

Made in the USA. This bottle is recyclable. Please support recycling in your community.

Packaging

Inner label - 473 ml
CLOSYS  FLUORIDE RINSE
sodium fluoride rinse

**Product Information**

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<thead>
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<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
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<tbody>
<tr>
<td>Route of Administration</td>
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**Active Ingredient/Active Moiety**

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<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>SODIUM FLUORIDE</td>
<td>FLUORIDE ION</td>
<td>0.05 g in 100 mL</td>
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**Inactive Ingredients**

<table>
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<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>CHLORINE DIOXIDE</td>
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</tr>
<tr>
<td>SODIUM PHOSPHATE, TRIBASIC, DODECAHYDRATE</td>
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<tr>
<td>ANHYDROUS CITRIC ACID</td>
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<tr>
<td>PEPPERMINT</td>
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<td>SUCRALOSE</td>
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### Product Characteristics

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<td>PEPPERMINT</td>
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### Packaging

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<th>Marketing End Date</th>
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<td>1 in 1 BOX</td>
<td>02/18/2016</td>
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<tr>
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### Marketing Information

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<td>OTC monograph final</td>
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<td>02/18/2016</td>
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**Labeler** - Rowpar Pharmaceuticals, Inc. (783704661)

Revised: 11/2019