

CLOSYS FLUORIDE RINSE- sodium fluoride rinse
Rowpar Pharmaceuticals, 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.

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 the 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

Specially formulated For Adults 55+

Non-Irritating: for Sensitive Mouths

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

Gentle MINT FLAVOR *with Fluoride*

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

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.

Oral Care as We Age

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.

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.

DISTRIBUTED BY:

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

Packaging



NET 3.4 fl oz (100 mL)
 IMPORTANT: Read directions for proper use.

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52534-10 2C-34-48F

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CLOSYS FLUORIDE RINSE

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58578-1234
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.05 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CHLORINE DIOXIDE (UNII: 8061YMS4RM)	
SODIUM PHOSPHATE, TRIBASIC, DODECAHYDRATE (UNII: B70850QPHR)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PEPPERMINT (UNII: V95R5KMY2B)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58578-1234-2	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/18/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/18/2016	

Labeler - Rowpar Pharmaceuticals, Inc. (783704661)