

CLOSYS SILVER SENSITIVE MOUTH RINSE FLUORIDE RINSE- sodium fluoride rinse

Rowpar Pharmaceuticals, Inc.

ClōSYS® Silver® Anticavity Fluoride Rinse

Drug Facts

Active ingredient

Sodium fluoride 0.02% (0.01% w/v fluoride ion)

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 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 twice a day after brushing your teeth with a toothpaste
- pour out and vigorously swish 10 milliliters 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

- consult a dentist or doctor

Other Information

- Do not use if safety seal is broken or missing.
- This rinse is not intended to replace brushing or flossing

Inactive ingredients

water, Cloralstan® (stabilized chlorine dioxide), trisodium phosphate, citric acid, peppermint flavor, sucralose

Questions or comments?

Call **1-800-643-3337**

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

CIōSYS®
SILVER®

Anticavity Fluoride Mouth Rinse

HEALTHY TEETH

SENSITIVE MOUTH RINSE

WITH FLUORIDE

HELPS REBUILD WEAKENED TOOTH
ENAMEL & REVERSE EARLY TOOTH DECAY

Protects Against Cavities

Freshens Breath

Non Burning, Alcohol Free

Gentle pH Balanced

Gentle Mint

32 fl oz (946 mL)

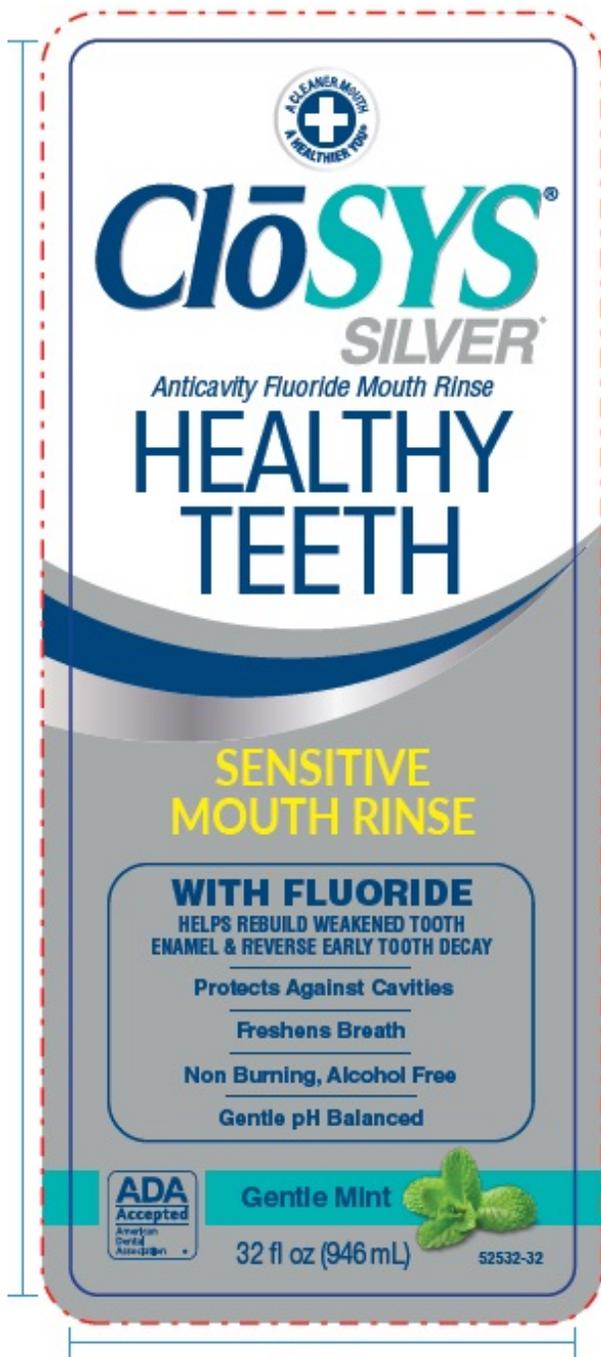
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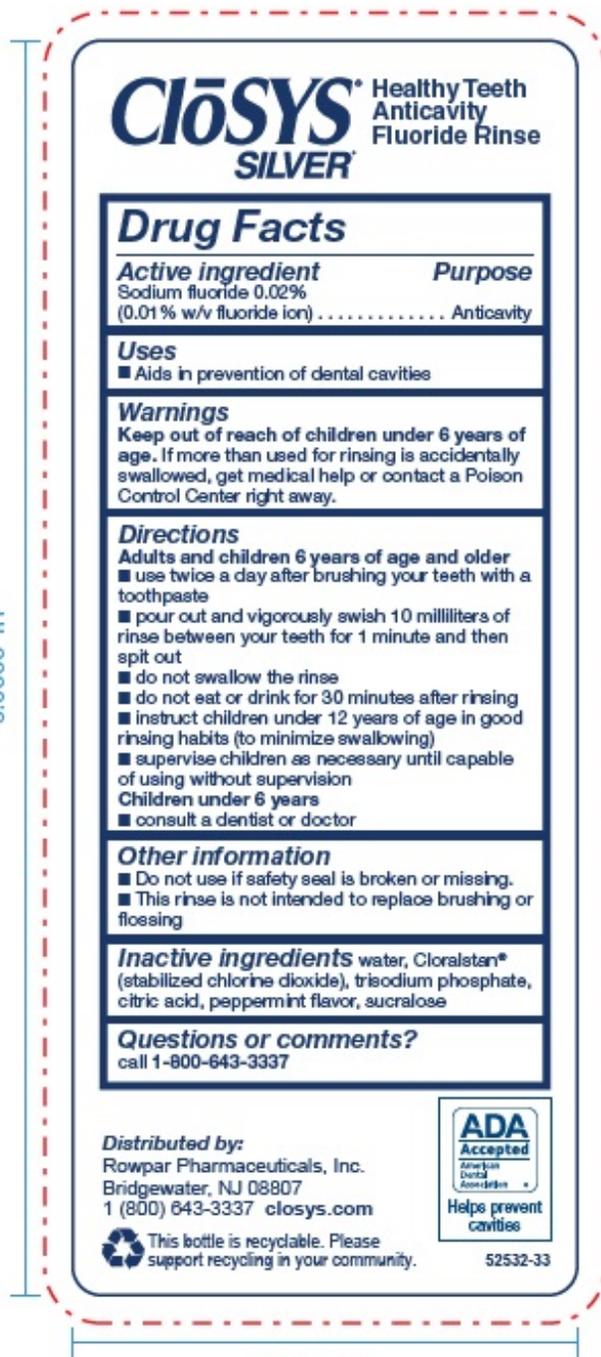
Rowpar Pharmaceuticals, Inc.
Bridgewater, NJ 08807
1 (800) 643-3337 **closys.com**

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support recycling in your community

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5.6000 in



Non-Burning, Non-Irritating Formula

A CLEANER MOUTH
A HEALTHIER YOU®

ClōSYS®
SILVER®

Anticavity Fluoride Mouth Rinse

HEALTHY
TEETH

SENSITIVE
MOUTH RINCE

WITH FLUORIDE

**HELPS REBUILD WEAKENED TOOTH
ENAMEL & REVERSE EARLY TOOTH DECAY**

Protects Against Cavities

Freshens Breath

Non Burning, Alcohol Free

Gentle pH Balanced

Gentle Mint

32 fl oz (946 mL)

A CLEANER MOUTH
A HEALTHIER YOU®

ClōSYS®
SILVER®

Serious Science for Sensitive Mouths™

**How does CloSYS® Silver
with Fluoride Work?**

CloSYS® Silver Healthy Teeth Mouth Rinse contains fluoride to help protect against cavities. With regular use, it helps rebuild weakened tooth enamel, reverse early tooth decay, and strengthen teeth to improve their appearance. The patented dual action formula contains Cloralstan® which kills bad breath bacteria and neutralizes sulfur mouth odor molecules for long lasting fresh breath. CloSYS® Silver Healthy Teeth Mouth Rinse does not contain alcohol, sulfates, triclosan, and other ingredients that can burn or irritate the mouth so you can rinse longer to get great results!

HEALTHY Mouth = HEALTHY Body

**Gentlest.
Oral Care.
Ever.®**

A CLEANER MOUTH
A HEALTHIER YOU®

ClōSYS®
SILVER®

Our Story

Founder of CloSYS® & Periodontist Dr. Perry Ratcliff had a bold belief that there had to be a better/gentler way to help with oral care. Dr. Ratcliff didn't agree with the common myth 'If it hurts, it must be good for you'

CloSYS® took a different approach—keep it gentle, yet effective, and people will use it long enough to make a difference in their oral health. After discovering that his first patented formula was not only extremely gentle but incredibly effective, he gathered a small group of dental professionals and business leaders to start their journey toward what is today CloSYS® Oral Care.

What Makes CloSYS® Product Different?

Simply put, CloSYS® is the Gentlest. Oral Care. Ever.® All CloSYS® formulas are highly effective and extremely gentle so they are not harsh or irritating to sensitive mouths. And because it's so gentle, it means you can swish it in your mouth longer without having to spit it out early and risk not getting the full benefit of the rinse.

CloSYS® products are free of alcohol, sulfates, triclosan, and other harsh ingredients that can burn or irritate sensitive mouths.

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CLOSYS SILVER SENSITIVE MOUTH RINSE FLUORIDE RINSE

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58578-0517
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION -	FLUORIDE ION	0.02 g in 100 mL

UNII:Q80VPU408O)	FLUORIDE ION	0.02 g in 100 mL
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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:58578-0517-1	1 in 1 BOX	01/01/2024	
1		473 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58578-0517-2	2 in 1 PACKAGE	01/01/2024	
2		946 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58578-0517-3	3 in 1 PACKAGE	01/01/2024	
3		946 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58578-0517-4	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	01/01/2023	

Labeler - Rowpar Pharmaceuticals, Inc. (783704661)