

CLOSYS- sodium fluoride paste, dentifrice
Rowpar Pharmaceuticals, Inc.

CloSYS® SILVER Gentle Fluoride TOOTHPASTE

Drug Facts

ACTIVE INGREDIENT:

Sodium fluoride 0.21% (0.11% w/v fluoride ion)

PURPOSE:

Anticavity

USES:

aids in the prevention of dental decay

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:

Adults and children 2 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 doctor.

Children under 6 years of age:

- instruct in good brushing and rinsing habits (to minimize swallowing).
- supervise children as necessary until capable of using without supervision.
- do not swallow

Children under 2 years of age:

Consult a dentist or doctor

INACTIVE INGREDIENTS:

water, hydrated silica, stabilized chlorine dioxide, cellulose gum, disodium hydrogen phosphate, titanium dioxide, peppermint oil, sodium dihydrogen phosphate, sodium myristoyl sarcosinate (coconut derived), sucralose, menthol crystals

Questions or comments?

Call 1-800-643-3337

Packaging

GENTLE MINT

A CLEANER MOUTH
A HEALTHIER YOU®

CLōSYS®
SILVER®

Gentlest. Oral Care. Ever®

for ADULTS 55+
MULTI-BENEFIT TOOTHPASTE

Anticavity Protection
Remineralizes Enamel
Freshens Breath
Gentle / Non-irritating

ADA Accepted
American Dental Association

3.4 oz
(96g)

ADA Accepted
American Dental Association
Helps prevent cavities

pH balanced

Naturally activated for faster results

Strengthens Enamel

SULFATE-FREE

Dist by:
Rowpar Pharmaceutical, Inc.
Scottsdale, AZ 85260
CloSYS.com

55034-37

MADE IN THE
USA

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Gentlest. Oral Care. Ever.®

SULFATE-FREE

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Use of stabilized chlorine dioxide is protected under U.S. & foreign patents-see CloSYS.com/patents

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54534-56

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Helps
prevent
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CLOSYS

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58578-0759
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.916 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
CHLORINE DIOXIDE (UNII: 8061YMS4RM)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
SODIUM MYRISTOYL SARCOSINATE (UNII: J07237209D)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58578-0759-1	1 in 1 BOX	01/06/2020	
1		96 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:58578-0759-2	1 in 1 BOX	01/06/2020	01/01/2024
2		21 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:58578-0759-3	2 in 1 PACKAGE	01/06/2020	
3		96 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	01/06/2020	

Labeler - Rowpar Pharmaceuticals, Inc. (783704661)

Revised: 5/2025

Rowpar Pharmaceuticals, Inc.