

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

CloSYS Fluoride Toothpaste

ACTIVE INGREDIENT:

Sodium fluoride 0.24% (0.13% w/v fluoride ion)

PURPOSE:

Anticavity

USE:

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, sarkosyl (coconut derived), disodium hydrogen phosphate, cellulose gum, titanium dioxide, peppermint oil, sodium dihydrogen phosphate, sucralose, menthol crystals

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

Questions or comments?

Call 1-800-643-3337

Principal Display Panel

Closys®
Anticavity Fluoride Toothpaste

SULFATE-FREE

NEW LOOK!

A CLEANER MOUTH
A HEALTHIER YOU®

CLOSYS®
Anticavity Fluoride Toothpaste

SENSITIVE
TOOTHPASTE
WITH FLUORIDE

NON-IRRITATING
SULFATE-FREE

HELPS REBUILD WEAKEND
TOOTH ENAMEL

Protects Against
Cavities

Freshens Breath

Non-Irritating
Formula

Gentle Mint

7oz (196g)

NON-IRRITATING
SULFATE-FREE

pH balanced

Fights
Cavities

Strengthens
Enamel

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Gentle Mint

3.4oz (96g)

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SENSITIVE TOOTHPASTE
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Non-Irritating Formula

Gentle Mint 3.4oz (96g)



sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58578-0749
Route of Administration	ORAL, DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
CHLORINE DIOXIDE (UNII: 8061YMS4RM)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
MENTHOL (UNII: L7T10EIP3A)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58578-0749-1	1 in 1 BOX	10/20/2017	
1		96 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:58578-0749-2	1 in 1 BOX	10/20/2017	
2		198 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:58578-0749-3	1 in 1 BOX	10/20/2017	06/30/2025
3		21 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	10/20/2017	

Labeler - Rowpar Pharmaceuticals, Inc. (783704661)

Establishment

Name	Address	ID/FEI	Business Operations
Transom Symphony OPCO, LLC		117501991	manufacture(58578-0749)

Revised: 12/2023

Rowpar Pharmaceuticals, Inc.