# **CLOSYS FLUORIDE RINSE-** sodium fluoride rinse Rowpar Pharmaceuticals, Inc.

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## CloSYS® Silver® ANTICAVITY 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 tsp) 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.

# OTHER INFORMATION:

Do not use if safety seal is broken or missing

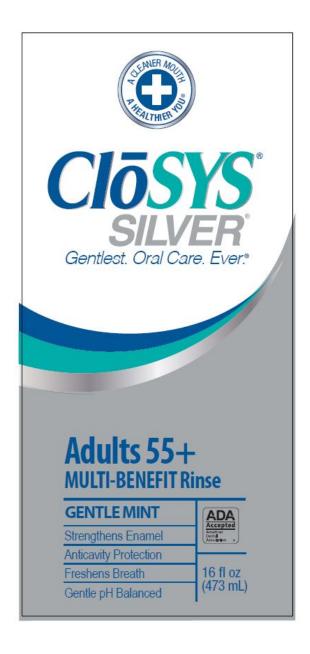
### **INACTIVE INGREDIENTS:**

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

Questions or comments? Call 1-800-643-3337

# **Packaging**

473ml Inner Label



FOR YOUR PROTECTION this bottle has a safety seal wrapped cap. DO NOT USE if the seal is broken. For maximum effectiveness store at room temperature.

### FOR ADULTS 55+

As we age the mouth may become more sensitive. CloSYS Silver helps strengthen enamel, fight cavities, and freshens breath with a gentle soothing formula.

# DRUG FACTS ACTIVE INGREDIENT Sodium fluoride 0.05% (0.02% w/v fluoride ion) Anticavity

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Questions or comments? Call 1-800-643-3337

### DIST BY:

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



This bottle is recyclable. Please support recycling in your community.

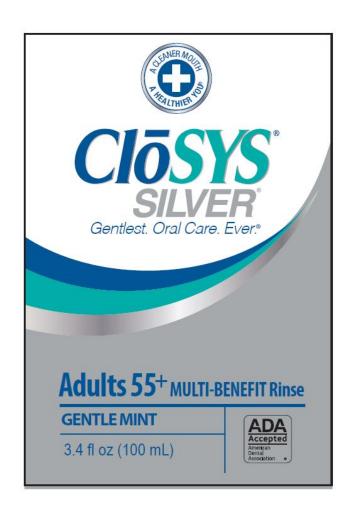
52516-22

47602 22701

473 mL Carton



100 ml Label



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.

### **DRUG FACTS**

**ACTIVE INGREDIENT** 

**PURPOSE** 

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

Anticavity

Use: Aids in the prevention of dental cavities

### DIRECTIONS FOR BEST RESULTS

- 1. Floss or Water Irrigate between teeth.
- 2. Brush-angle 45° into gum line, spit excess.
- 3. Rinse for 1 minute with 1 capful, gargle spit excess.
- 4. Try not to eat or drink for 30 minutes for maximum effect.

INACTIVE INGREDIENTS: Water, Stabilized Chlorine Dioxide, Trisodium Phosphate, Citric Acid, Peppermint Flavor, Sucralose

**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. Do not swallow.

#### DIST BY

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





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52534-16

# **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

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)

Basis of Strength
Strength
FLUORIDE ION
0.05 g in 100 mL

# **Inactive Ingredients**

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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				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:58578- 1234-1	1 in 1 BOX	02/18/2016		
1		473 mL in 1 BOTTLE; Type 0: Not a Combination Product			
2	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 Drug	M021	02/18/2016	

# **Labeler -** Rowpar Pharmaceuticals, Inc. (783704661)

Revised: 12/2023 Rowpar Pharmaceuticals, Inc.