CLOSYS- hydrogen peroxide rinse Rowpar Pharmaceuticals, Inc.

CloSYS Mouth Sores Oral Rinse

Drug Facts

Active ingredient

Hydrogen Peroxide 1.5% (w/v)

Purpose

Oral debriding agent Oral wound cleanser

Uses

- For temporary use to cleanse canker sores and minor wounds or minor gum inflammation resulting from dental procedures, dentures, orthodontic appliances, accidental injury, or other irritations of the mouth and gums.
- Assist in the removal of foreign material from minor oral wounds.

Warnings

Do not use this product for more than 7 days unless directed by a dentist, or physician.

When using this product, do not swallow.

Stop use and ask a doctor if

- sore mouth symptoms do not improve within 7 days.
- irritation, pain or redness persists or worsens.
- swelling, rash or fever develops.

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 12 years of age and older

- Use 10 mL (two teaspoons) around in the mouth over affected areas for at least 1 minute and spit out
- Use up to 4 times daily after meals and at bedtime or as directed by a dentist or physician

Children 6 years to under 12 years of age: supervise use

Children under 6 years of age: do not use

Other Information

- Do not use if safety seal is broken or missing
- Cap tightly
- Keep away from direct sunlight
- Store at room temperature, 68 to 77°F (20 to 25°C)

Inactive ingredients

water, polypropylene glycol, flavors, polysorbate 20, polysorbate 80, sucralose, disodium EDTA, menthol, citric acid

Questions or comments?

call **1-800-643-3337**

Packaging

A CLEANER MOUTH A HEALTHIER YOU®

CLoSYS®

Oral Debriding Agent

MOUTH SORES

SENSITIVE MOUTH RINSE

PROMOTES HEALING

HELPS CLEANSE & PROMOTE HEALING OF ORAL SORES, MOUTH BURNS & IRRITATION

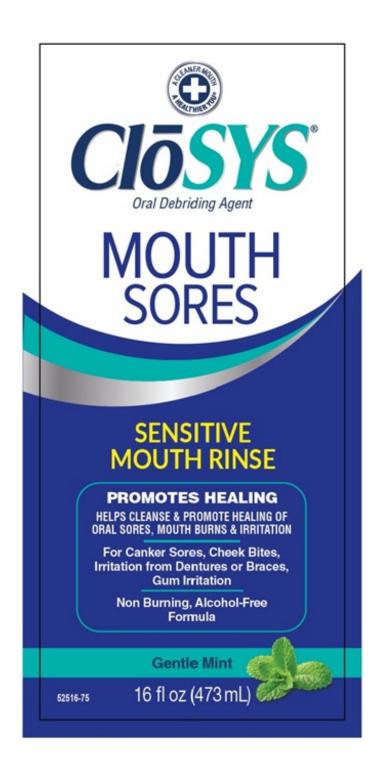
For Canker Sores, Cheek Bites, Irritation from Dentures or Braces, Gum Irritation

Non Burning, Alcohol-Free Formula

Gentle Mint

16 fl oz (473mL)

52516-75



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

52516-76

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CLOSYS

hydrogen peroxide rinse

Product Information

Product Type HUMAN OTC DRUG Item

Item Code (Source) NDC:58578-0613

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of
Strength

Strength

Inactive Ingredients			
Ingredient Name	Strength		
Water (UNII: 059QF0KO0R)			
Propylene Glycol (UNII: 6DC9Q167V3)			
Polysorbate 20 (UNII: 7T1F30V5YH)			
Polysorbate 80 (UNII: 60ZP39ZG8H)			
Sucralose (UNII: 96K6UQ3ZD4)			
Edetate Disodium (UNII: 7FLD91C86K)			
Menthol, Unspecified Form (UNII: L7T10EIP3A)			
Citric Acid Monohydrate (UNII: 2968PHW8QP)			

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	PEPPERMINT	Imprint Code		
Contains				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:58578- 0613-1	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	01/27/2025	

Labeler - Rowpar Pharmaceuticals, Inc. (783704661)

Revised: 1/2025 Rowpar Pharmaceuticals, Inc.