

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



ClōSYS®

Oral Debriding Agent

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Gentle Mint



52516-75

16 fl oz (473 mL)

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

52516-76

Drug Facts

| Active ingredient | Purpose |
|--|---|
| Hydrogen Peroxide 1.5% (w/v) | Oral debriding agent Oral wound cleanser |

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52516-76

CLOSYS

hydrogen peroxide rinse

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58578-0613 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | |
|---|-------------------|--------------------|
| Hydrogen Peroxide (UNII: BBX060AN9V) (Hydrogen Peroxide - UNII:BBX060AN9V) | Hydrogen Peroxide | 1.5 g in 100 mL |
|---|-------------------|--------------------|

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| Water (UNII: 059QF0KO0R) | |
| Propylene Glycol (UNII: 6DC9Q167V3) | |
| Polysorbate 20 (UNII: 7T1F30V5YH) | |
| Polysorbate 80 (UNII: 6OZP39ZG8H) | |
| 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 |
| 1 | NDC:58578-0613-1 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/27/2025 | |
| 2 | NDC:58578-0613-5 | 1 in 1 CARTON | 01/01/2026 | |
| 2 | | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 3 | NDC:58578-0613-7 | 3 in 1 PACKAGE | 11/18/2025 | |
| 3 | | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

| 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)

| Establishment | | | |
|----------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| Geodis Logistics LLC | | 116937615 | pack(58578-0613) |

