PREVENTION MOUTH RINSE- hydrogen peroxide liquid Prevention Health Sciences, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Prevention Mouth Sore Relief

Drug Facts

Active ingredient

Hydrogen peroxide 1.5%

Purpose

Oral debriding agent / Antiseptic

Uses

- first aid to help reduce the risk of infection in minor cuts and scrapes caused by
- dentures
- dental procedures
- orthodontic appliances
- accidental injury
- aids in the removal of phlegm, mucus or other secretions associated with occasional sore mouth
- for temporary use to cleanse canker sores, minor wounds and gum irritation

Warnings

Do not use for more than 7 days unless directed by a dentist or doctor

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 2 years of age and older: swish one capful (10 ml) around in mouth over affected area for at least one minute and then spit out
- use up to 4 times daily, after meals and at bedtime or as directed by a dentist or doctor
- children under 12 should be supervised in the use of product.
- children under 2 years of age: consult a dentist or doctor.

Other information

• keep away from heat or direct sunlight

• Do not use if safey seal under cap is broken or missing

Inactive ingredients De-ionized water, glycerin, poloxamer 407, sodium lauryl sulfate, disodium EDTA, Mentha piperita (peppermint) oil, sodium citrate, sodium saccharin, citric acid, zinc chloride, menthol

Questions? call (800) 473-1205

Formulated and Distribured by:

Prevention Health Sciences, Inc.

Raleigh, IL 62977

800-473-1205

PHS Brands

ALCOHOL FREE

PREVENTION™ MOUTH RINSE

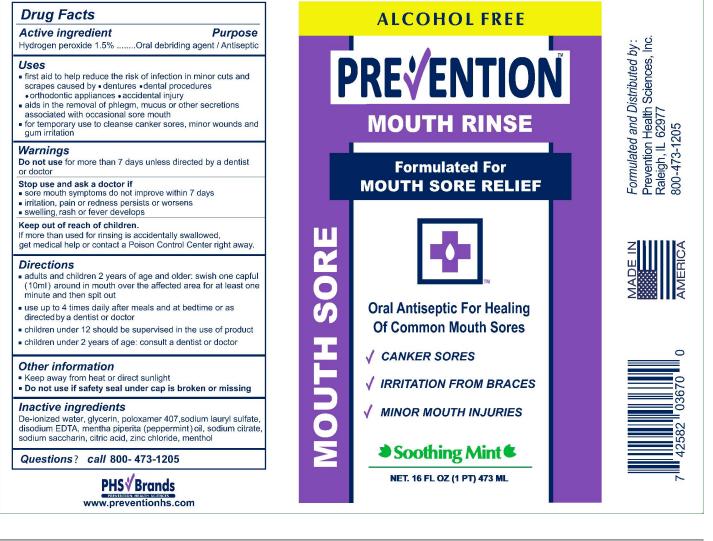
Formulated for MOUTH SORE RELIEF

Oral Antiseptic for Healing of Common Mouth Sores

- CANKER SORES
- IRRITATION FROM BRACES
- MINOR MOUTH INJURIES

Soothing Mint

NET. 16 FL OZ (1 PT) 473 ML



| PREVENTION MOUTH | H RINSE | | | | | |
|--|------------------|--------------------|--|---------------|---------------|--|
| Due duet Information | | | | | | |
| Product Information | | | | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | | NDC:69951-002 | | |
| Route of Administration | TOPICAL | | | | | |
| | | | | | | |
| Active Ingredient/Active | Moiety | | | | | |
| Ingredient Name Basis of Strength | | | | | Strength | |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - HYDROGEN PEROXIDE - UNII: BBX060AN9V) PEROXIDE | | | | | 5 g 100 mL | |
| | | | | | | |
| Inactive Ingredients | | | | | | |
| Ingredient Name | | | | | Strength | |
| CITRIC ACID MONOHYDRATE (UI | III: 2968PHW8QP) | | | | | |
| WATER (UNII: 059QF0KO0R) | | | | | | |
| EDETATE DISODIUM (UNII: 7FLD9 | 1C86K) | | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | | | |

| MENTHOL (UNII: L | .7T10EIP3A) | | | | | |
|-------------------------------|---|----------------------------|-----------|-------------------------|-----------------------|--|
| PEPPERMINT OIL | (UNII: AV092KU4JH |) | | | | |
| POLOXAMER 407 | (UNII: TUF2IVW3M2 | 2) | | | | |
| SODIUM CITRATE | UNII: 1Q73Q2JUL | R) | | | | |
| ZINC CHLORIDE | (UNII: 86Q357L16B) | | | | | |
| SODIUM LAURYL | | | | | | |
| SACCHARIN SOD | IUM (UNII: SB8ZUX | (40TY) | | | | |
| | | | | | | |
| Product Char | acteristics | | | | | |
| Color | | | Score | | | |
| Shape | | | Size | | | |
| Flavor | MINT Imprint Code | | | | | |
| Contains | | | • | | | |
| | | | | | | |
| | | | | | | |
| Packaging | | | | | | |
| # Item Code | Рас | Package Description | | Marketing Start Date | Marketing End Date | |
| 1 NDC:69951- 002-16 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | | 10/01/2023 | | |
| | | | | | | |
| Marketing | Informatio | on | | | | |
| Marketing Category | Applicatio | on Number or I Citation | Monograph | Marketing Start Date | Marketing End Date | |
| OTC monograph n final | ot part356 | | | 10/01/2023 | | |
| | | | | | | |

Labeler - Prevention Health Sciences, Inc. (968930540)

Revised: 10/2023

Prevention Health Sciences, Inc.