

PEROXYL MOUTH SORE MILD MINT - hydrogen peroxide rinse
Colgate Oral Pharmaceuticals, 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.

PEROXYL[®] MOUTH SORE RINSE MILD MINT

Drug Facts

Active ingredient (in each 10 mL)

Hydrogen peroxide 150 mg

Purpose

oral debriding agent

Use

oral debriding agent/oral wound cleanser for temporary use to cleanse canker sores and minor wounds or minor gum inflammation resulting from minor dental procedures, dentures, orthodontic appliances, accidental injury, or other irritations of the mouth and gums such as mouth burns, cheek bites and toothbrush abrasions.

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 2 years of age and older: rinse contents of this package (two teaspoons) around in the mouth over affected area for at least 1 minute, then spit out
- use up to 4 times daily after meals and at bedtime or as directed by dentist or physician
- children under 12 years of age should be supervised in the use of the product
- children under 2 years of age: consult a dentist or physician

Other information

store at controlled room temperature 20-25° C (68-77° F)

Inactive ingredients

water, sorbitol, propylene glycol, poloxamer 338, polysorbate 20, methyl salicylate, menthol, sodium saccharin, FD&C blue no.1

Questions?

1-800-962-2345

PRINCIPAL DISPLAY PANEL - 50 Packet Carton

Colgate®

Peroxyl®

MOUTH SORE

RINSE

ALCOHOL-FREE

1.5% Hydrogen Peroxide

MILD MINT

50 Unit Dose Packets 0.34 FL OZ (10 mL) Each

TOTAL 17 FL OZ (1.06 PT) 502 mL

Colgate®

Peroxyl®

**MOUTH SORE
RINSE**

ALCOHOL-FREE

15% Hydrogen Peroxide

MILD MINT

50 Unit Dose Packets 0.34 FL OZ (10 mL) Each
TOTAL 17 FL OZ (1.06 PT) 502 mL

Colgate®

Peroxyl®

**MOUTH SORE
RINSE**

ALCOHOL-FREE

Oxygenating Action
removes oral debris.
This facilitates healing and
helps alleviate discomfort.

RECOMMENDED FOR:

Canker Sores

Mouth Burns

Cheek Bites

Denture & Mouth Sores

Orthodontic Abrasion

Minor Gum Inflammation

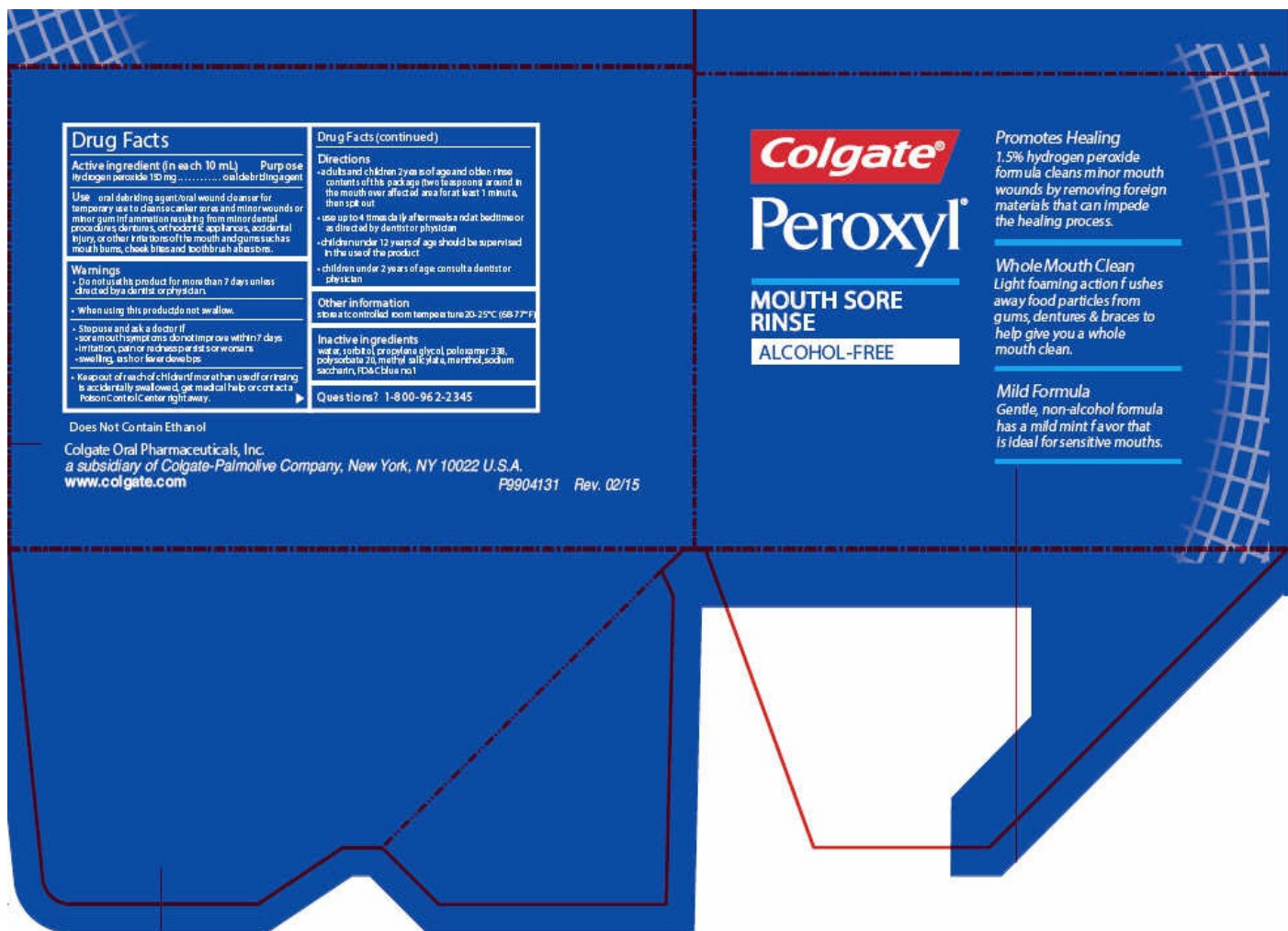


ALCOHOL-FREE

MOUTH SORE
RINSE

Peroxyl®

Colgate®



Drug Facts

Active ingredient (in each 10 mL) Purpose Hydrogen peroxide 150 mg oral debriding agent

Use oral debriding agent/oral wound cleanser for temporary use to cleanse canker sores and minor wounds or minor gum inflammation resulting from minor dental procedures, dentures, orthodontic appliances, accidental injury, or other irritations of the mouth and gums such as mouth burns, cheek bites and toothbrush abrasions.

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:
 - sores or mouth sores do not improve within 7 days
 - irritation, pain or redness persists or worsens
 - swelling, rash or fever develops
- Keep out of reach of children. More than one use or rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions

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Does Not Contain Ethanol

Colgate Oral Pharmaceuticals, Inc.
a subsidiary of Colgate-Palmolive Company, New York, NY 10022 U.S.A.
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Colgate®

Peroxyl®

MOUTH SORE RINSE

ALCOHOL-FREE

Promotes Healing
1.5% hydrogen peroxide formula cleans minor mouth wounds by removing foreign materials that can impede the healing process.

Whole Mouth Clean
Light foaming action flushes away food particles from gums, dentures & braces to help give you a whole mouth clean.

Mild Formula
Gentle, non-alcohol formula has a mild mint flavor that is ideal for sensitive mouths.

PEROXYL MOUTH SORE MILD MINT

hydrogen peroxide rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0126-0083
Route of Administration	BUCCAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrogen Peroxide (UNII: BBX060AN9V) (Hydrogen Peroxide - UNII:BBX060AN9V)	Hydrogen Peroxide	15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Sorbitol (UNII: 506T60A25R)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Poloxamer 338 (UNII: F75JV2T505)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
Polysorbate 20 (UNII: 7T1F30V5YH)	

Saccharin Sodium (UNI: SB8ZUX40TY)

Product Characteristics

Color	BLUE (Light Blue Solution with the Smell of Mint)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0126-0083-70	50 in 1 CARTON		
1		10 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	01/01/2009	

Labeler - Colgate Oral Pharmaceuticals, Inc. (055002195)

Revised: 9/2015

Colgate Oral Pharmaceuticals, Inc.