

PEROXYL MOUTH SORE MILD MINT - hydrogen peroxide rinse

Colgate Oral Pharmaceuticals, Inc.

Reference Label Set Id: 818575ec-5136-4d4f-a0d4-51a7770499be

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 Mild Mint

Drug Facts

Active ingredient

Hydrogen peroxide 1.5% (w/v)

Purposes

Oral debriding agent/oral wound cleanser

Uses

- 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

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 half a capful (two teaspoons or 10 mL) 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 a 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

Inactive ingredients

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

Other Information

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

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

PRINCIPAL DISPLAY PANEL - 500 mL Bottle Label

ALCOHOL FREE*

Colgate®

Oral Debriding Agent

Peroxyl®

Mouth Sore Rinse |

1.5% Hydrogen

Peroxide

CLEANSSES & PROMOTES HEALING
OF MINOR ORAL WOUNDS

HELPS PROMOTE HEALING OF:

- ORAL SORES
- IRRITATIONS
- MOUTH BURNS

MILD MINT

16.9 FL OZ

(1.05 PT)

500 mL

Helps Promote Healing

P9933376

ALCOHOL FREE*

Colgate®

Oral Debriding Agent

Peroxyl®

Mouth Sore Rinse | 1.5% Hydrogen Peroxide



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P 9033078

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*Does Not Contain Ethyl Alcohol
CAP SEALED WITH PRINTED BAND



Dist. by:
COLGATE-PALMOLIVE COMPANY
New York, NY 10022 U.S.A.
www.colgate.com

P9918159



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
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HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	15 mg in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLOXAMER 338 (UNII: F75JV2T505)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0126-0083-16	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2009	
2	NDC:0126-0083-99	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2015	
3	NDC:0126-0083-70	50 in 1 CARTON	03/15/2017	
3		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. (968801118)

Revised: 12/2019

Colgate Oral Pharmaceuticals, Inc.