

ANTISEPTIC MOUTH SORE- hydrogen peroxide, menthol rinse
CVS Pharmacy

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.

CVS Pharmacy, Inc. Antiseptic Mouth Sore Rinse Drug Facts

Active Ingredient

Hydrogen peroxide 1.5%

Menthol 0.1%

Purpose

Oral debriding agent/Oral wound cleansing

Oral pain reliever

Uses

- For temporary use in cleansing minor wounds or gum inflammation resulting from minor dental procedures, dentures, orthodontic appliances, accidental injury, canker sores, or other irritations of the mouth and gums.
- For temporary relief of pain associated with canker sores

Warnings

Do not use

this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persists or worsens; or if swelling, rash, or fever develops, stop use and see your dentist or doctor promptly.

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 and older

- Swish one-half capful (2 teaspoons=10mL) around the mouth over the affected area for at least 1 minute and then spit out. Use up to 4 times daily after meals and at bedtime or as directed by a dentist or doctor. Do not swallow.

- Children under 12 years of age should be supervised in the use of this product.

Children under 2 years of age: Consult a dentist or doctor.

Other Information

- Do not use if printed safety seal is broken or missing
- Recommended storage temperature 59°-77°F (15°-25°C)

Inactive Ingredients

Purified Water, Sorbitol, Poloxamer 407, PEG-40 Hydrogenated Castor Oil, Flavor, Sodium Benzoate, Sodium Saccharin, Xylitol, Citric Acid

Package/Label Principal Display Panel

ALCOHOL FREE

CVS Health®

Compare to the active ingredients in Orajel® Antiseptic Rinse

Antiseptic Mouth Sore Rinse

ORAL DEBRIDING AGENT / ORAL WOUND CLEANSER

- Dye Free

- Promotes healing & cleans oral wounds

- Relieves pain from canker sores, cheek bites, gum irritation & dental work

Fresh Mint

16 FL OZ (473 mL)

LFA4317F1



ANTISEPTIC MOUTH SORE			
hydrogen peroxide, menthol rinse			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-515
Route of Administration	PERIODONTAL		
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
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)		MENTHOL, UNSPECIFIED FORM	1 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
POLOXAMER 407 (UNII: TUF2IVW3M2)			
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			

XYLITOL (UNII: VCQ006KQ1E)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-515-43	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/18/2021	

Labeler - CVS Pharmacy (062312574)

Revised: 1/2022

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