ANTISEPTIC MOUTH RINSE- eucalyptol mouthwash Perrigo Direct, 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.

Spring Mint Antiseptic Mouthrinse 072AL rev2-AN

Active Ingredients

Eucalyptol 0.092%, Menthol 0.042% Methyl salicylate 0.060%, Thymol 0.064%

Purpose

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Antigingivitis, Antiplaque

Use

helps control plaque that leads to gingivitis

Warnings

for this product

Do not use

if you have painful or swollen gums, pus from the gum line, loose teeth or increased spacing between the teeth. See you dentist immediately. These may be signs of periodontitis, a serious form of gum disease.

Stop use and ask a dentist if

gingivitis, bleeding, or redness persists for more than 2 weeks.

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 - Vigorously swish 20 ml (2/3 FL OZ or 4 teaspoonfuls) between teeth for 30 seconds then spit out; do not swallow

Children under 12 years of age -Consult a dentist or doctor

This rinse is not intended to replace brushing or flossing

Other information

cold weather may cloud this product. Its antiseptic properties are not affected. Store at room temperature (59° - 77° F)

Inactive ingredients

water, alcohol 21.6%, sorbitol, poloxamer 407, benzoic acid, sodium saccharin, flavor, sodium citrate, yellow 10, green 3

*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine

Distributed by: Perrigo Direct, Inc.

Peachtree City, GA 30269

1-888-593-0593

GoodSense is a registered trademark of L. Perrigo Company

DSP-TN-21091

DSP-MO-20087

Principal Panel Display

Sealed With Printed Neckband For your Protection

GoodSense

NDC 50804-072-86 ANTISEPTIC MOUTH RINSE

Spring Mint

ADA Accepted

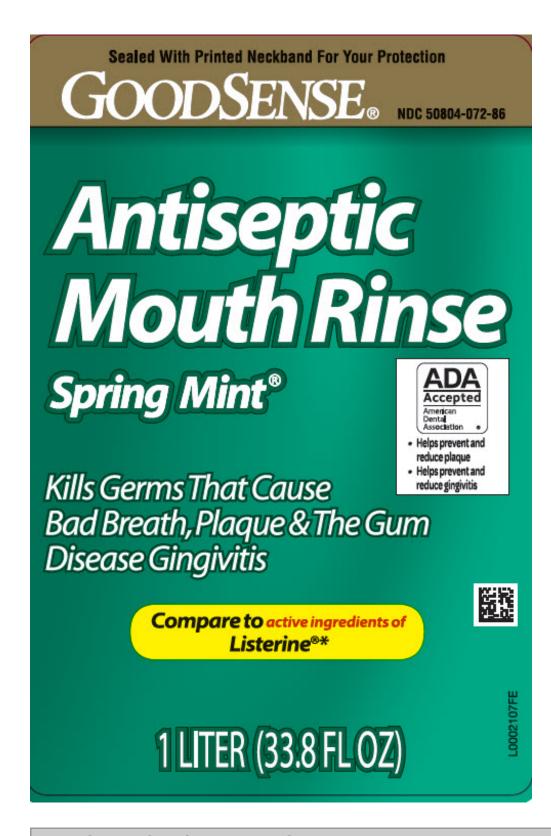
American Dental Association

- Helps prevent and reduce plaque
- Helps prevent and reduce gingivitis

Kills germs that cause bad breath, plaque & the gum disease gingivitis

Compare to the Active Ingredients in Listerine*

1 LITER (33.8 FLOZ)



ANTISEPTIC MOUTH RINSE

eucalyptol mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-072
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.92 mg in 1 mL	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.42 mg in 1 mL	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: O414PZ4LPZ)	METHYL SALICYLATE	0.6 mg in 1 mL	
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
Water (UNII: 059QF0KO0R)			
ALCOHOL (UNII: 3K9958V90M)			
SORBITOL (UNII: 506T60A25R)			
POLOXAMER 407 (UNII: TUF2IVW3M2)			
BENZOIC ACID (UNII: 85KN0B0MIM)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50804- 072-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/15/2009	
2	NDC:50804- 072-69	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/15/2009	

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
part348	08/15/2009		
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date	

Labeler - Perrigo Direct, INC. (076059836)

Registrant - Vi Jon (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi Jon		790752542	manufacture(50804-072)	

Establishment			
Name	Address	ID/FEI	Business Operations
Vi Jon		088520668	manufacture(50804-072)

Revised: 10/2022 Perrigo Direct, INC.