

**ANTISEPTIC MOUTH RINSE- eucalyptol mouthwash
Walgreens Co.**

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.

Walgreens Antiseptic Mouth Rinse 072.003-072A1 rev 2/072AN

Active ingredients

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

Purpose

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 your 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, flavor, poloxamer 407, benzoic acid, sodium saccharin, sodium citrate, D+C yellow no. 10, FD+C green no.3

ADA Statement

The ADA Council on Scientific Affairs Acceptance of Walgreens Spring Mint Antiseptic Mouth Rinse is based on its finding that the product is effective in helping to prevent and reduce gingivitis and plaque above the gumline, when used as directed.

Disclaimer

This product is not manufactured or distributed by Johnson + Johnson Healthcare products, distributor of Listerine Fresh Burst

DSP-TN-1500 DSP-MO-34 SDS-TN-15012

principal display panel

Well at Walgreens

ANTISEPTIC

Mouth Rinse

Antigingivitis / Antiplaque

- Freshens breath
- Improves oral hygiene
- Alcohol 21.6%

ADA

Accepted

American

Dental

Association

SPRING MINT

Compare to FreshBurst Listerine

Antiseptic Mouthwash active ingredients

16.9 FL OZ (500 mL)

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SPRING
MINT®

Compare to FreshBurst Listerine®
Antiseptic Mouthwash active ingredients#

16.9 FL OZ (500 mL)

L0015447FB

ANTISEPTIC MOUTH RINSE

eucalyptol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0072
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.092 kg in 100 L
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.042 kg in 100 L
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.060 kg in 100 L
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.064 kg in 100 L

Inactive Ingredients

Ingredient Name	Strength
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water (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR601S)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT (Spring Mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0072-77	0.5 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2007	
2	NDC:0363-0072-86	1 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2007	
3	NDC:0363-0072-12	1.5 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2007	
4	NDC:0363-0072-13	1.25 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2007	
5	NDC:0363-0072-88	2 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2007	
6	NDC:0363-0072-69	.25 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/30/2007	

Labeler - Walgreens Co. (008965063)

Registrant - Vi Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon		790752542	manufacture(0363-0072)