

ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash
Better Living Brands LLC

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.

Drug Facts

TEP

Sealed with printed neckband for your protection

Active ingredients

Eucalyptol 0.092%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

Purpose

Antigingivitis, antiplaque

Use

help 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 solution, flavoring, poloxamer 407, benzoic acid, sodium saccharin, sodium citrate, D&C yellow no. 10, FD&C green no.3

ADA Council Statement

The ADA Council on Scientific Affairs Acceptance of Signature Care Spring Mint Antiseptic Mouthwash 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

Adverse Reactions

DISTRIBUTED BY BETTER LIVING BRANDS LLC

P.O. BOX 99, PLEASANTON, CA 94566-0009

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principal display panel

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Care

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ANTISEPTIC

Mouthwash

antigingivitis/antiplaque

Spring Mint

Fights Plaque & Gingivitis

ADA

Accepted

American

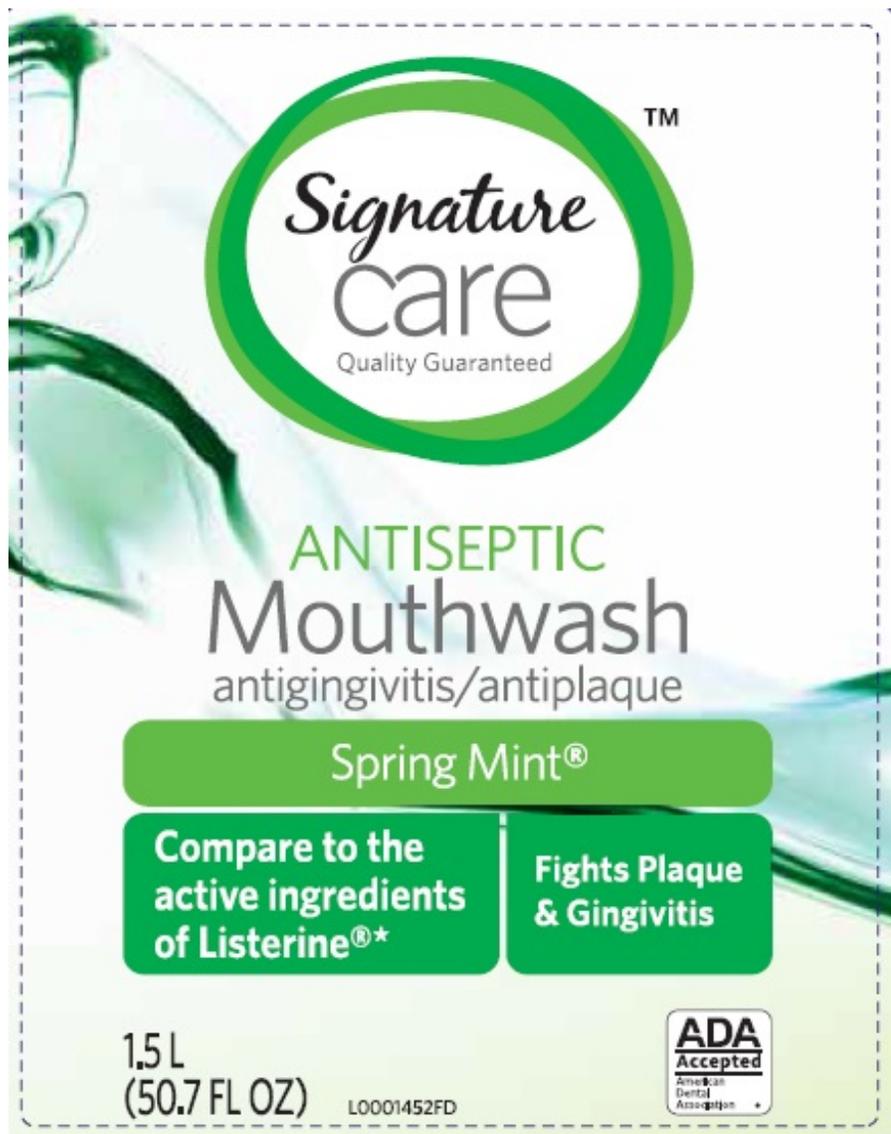
Dental

Association

Compare to the active ingredients of Listerine

1.5 L

(50.7 FL OZ)



ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-072
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: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	MENTHOL	0.42 mg in 1 mL
		METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.60 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: 8SKN0B0MM)		
		SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
		SODIUM CITRATE (UNII: 1Q73Q2JULR)		
		D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
		FD&C GREEN NO. 3 (UNII: 3P3ONR601S)		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-072-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/25/1998	
2	NDC:21130-072-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/25/1998	
3	NDC:21130-072-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/25/1998	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part356	03/25/1998	

Labeler - Better Living Brands LLC (009137209)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(21130-072)