

ANTISEPTIC MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash Shopko

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

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

Disclaimer

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

Adverse Reactions Section

Distributed by Shopko Stores Operating CO., LLC

Green Bay, WI, 54307

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www.shopko.com

072.002/072AL

principal display panel

SHOPKO

COMPARE TO THE ACTIVE INGREDIENTS OF LISTERINE

Antiseptic

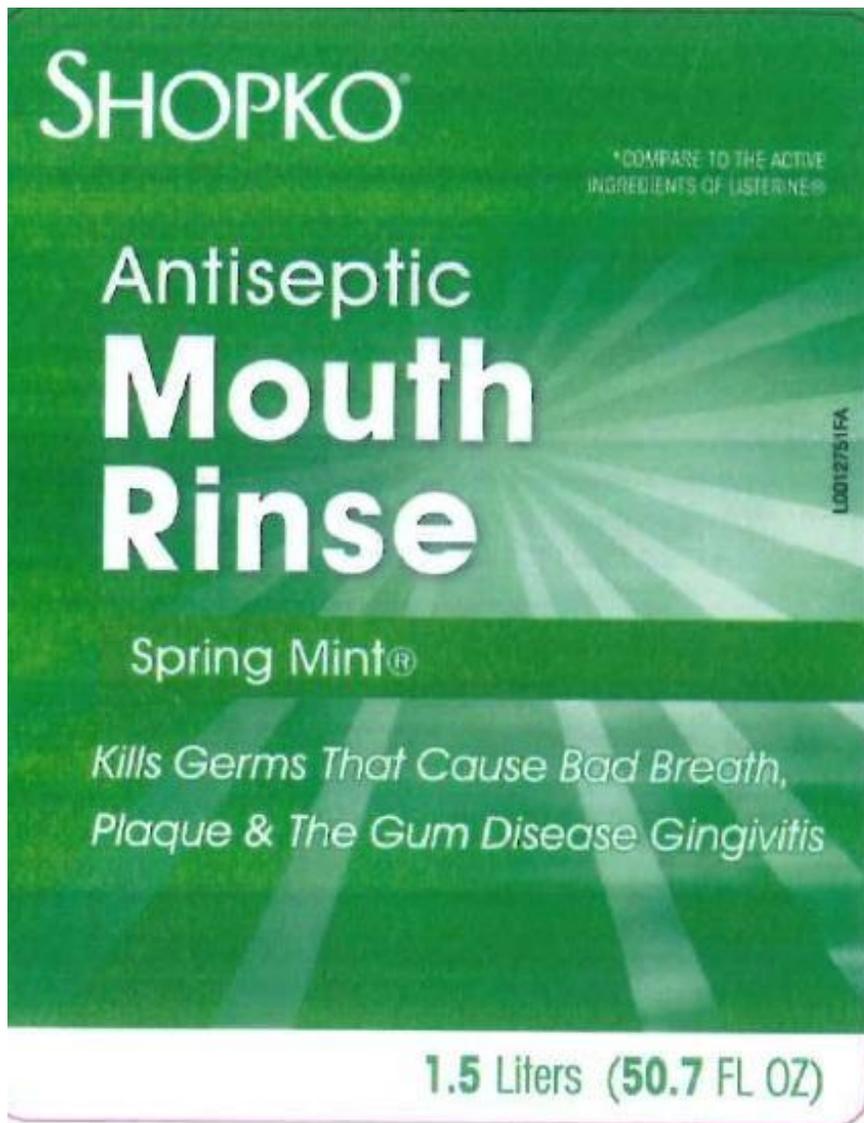
Mouth

Rinse

Spring Mint

Kills Germs That Cause Bad Breath, Plaque & The Gum Disease Gingivitis

1.5 Liters (50.& FL OZ)



ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-072
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	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: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

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:370 12-072-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/08/2008	
2	NDC:370 12-072-13	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/08/2008	
3	NDC:370 12-072-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/08/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/08/2008	

Labeler - Shopko (023252638)

Registrant - Vi Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon		790752542	manufacture(370 12-072)