

SHOPKO SPRING MINT- eucalyptol, menthol, methyl salicylate, thymol mouthwash
Apollo Health and Beauty Care 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.

Drug Facts

Active ingredients

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

Purpose

Antiplaque/Antigingivitis

Uses

helps reduce plaque that leads to

- gingivitis
- bleeding gums

Warnings

Stop use and ask a dentist if

- gingivitis, bleeding, or redness persists for more than 2 weeks.
- you have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.

Keep out of reach of children under 6 years of age.

If more than used for rinsing is accidentally swallowed, get medical help or contact Poison Control Center immediately.

Directions

- Adults and children 12 years of age and older: vigorously swish 20 milliliters of rinse between your teeth twice a day for 30 seconds and then spit out. Do not swallow the rinse.
- children 6 years to under 12 years of age: supervise use.
- children under 6 years of age: do not use.

Other information

- This rinse is not intended to replace brushing or flossing.
- Store at room temperature. Cold weather may cloud this product. Its antiseptic properties are not affected.

Inactive ingredients

Water (Aqua), Alcohol (21.6%), Sorbitol, Flavor, Poloxamer 407, Benzoic Acid, Sodium Saccharin, Sodium Benzoate, Yellow 10 (CI 47005), Green 3 (CI 42053).

Questions or comments?

1-866-695-3030

Label copy



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MADE IN CANADA
Manufactured by:
Apollo Health & Beauty Care Inc. 1 Apollo Place,
Toronto, ON M3J 0H2
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Johnson & Johnson Consumer Inc., owner of the
registered trademarks Listerine® and Freshburst®.

****To open, squeeze cap and turn. To close, turn cap until it clicks.
*Do not use if printed band around cap is broken or missing.**

By Refund or Exchange

06-23501

0 10994 00188 4

0 00000 00000 0

SHOPKO SPRING MINT

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63148-009
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 BENZOATE (UNII: OJ245FE5EU)	
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:63148-009-50	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/07/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	06/07/2018		

Labeler - Apollo Health and Beauty Care Inc. (201901209)

Registrant - Apollo Health and Beauty Care Inc. (201901209)

Establishment			
Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(63148-009)