HYVEE ANTISEPTIC ORIGINAL- eucalyptol, menthol, methyl salicylate, thymol liquid HYVEE 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

to help reduce and prevent plaque and gingivitis.

Warnings

Do not use in children under 12 years of age.

Keep out of reach of children.

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

Directions

- Rinse full strength for 30 seconds with 20 mL (2/3 fluid ounce or 4 teaspoonfuls) morning and night.
- Do not swallow.

Other information

- Store at room temperature.
- Cold weather may cloud this product. Its antiseptic properties are not affected.

Inactive ingredients

Water (Aqua), Alcohol (26.9%), Benzoic Acid, Poloxamer 407, Sodium Benzoate, Caramel.

Questions or comments?

1-800-289-8343

Label Copy



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DISTRIBUTED BY HY-VEE, INC. WEST DES MOINES, IA 50266 MADE IN CANADA

SATISFACTION GUARANTEED CALL 1-800-289-8343 www.hy-vee.com

This product is not manufactured or distributed by McNeil-PPC, Inc., owner of the registered trademark Listerine.

DO NOT USE IF PRINTED BAND AROUND CAP IS BROKEN OR MISSING.

TO OPEN: SQUEEZE SMOOTH AREAS ON CAP AND TURN. TO CLOSE: TURN CAP UNTIL IT LOCKS.



HYVEE ANTISEPTIC ORIGINAL

eucalyptol, menthol, methyl salicylate, thymol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42507-556	
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: 3J50 XA376E) (THYMOL - UNII:3J50 XA376E)	THYMOL	0.64 mg in 1 mL	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
ALCOHOL (UNII: 3K9958V90M)				
BENZO IC ACID (UNII: 8 SKN0 B0 MIM)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
CARAMEL (UNII: T9D99G2B1R)				

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Packaging		

#	Item Code	Package Description	Date	Date
1	NDC:42507-556- 50	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing Information				
	Marketing Categ	ory Application Number or Monograph Citation I	Marketing Start Date	Marketing End Date
О	TC monograph not	final part356 0	3/02/2016	

Labeler - HYVEE INC (006925671)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(42507-556)	

Revised: 3/2016 HYVEE INC