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 FOR 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.

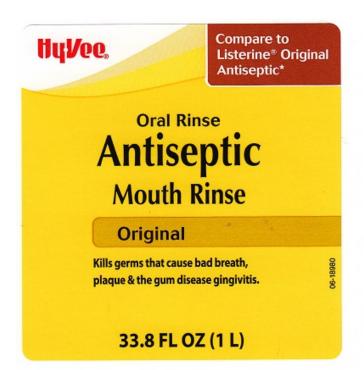
INACTIVE INGREDIENTS:

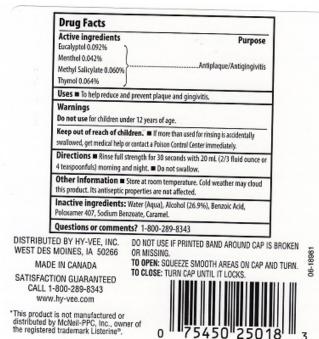
WATER (AQUA), ALCOHOL (26.9%), BENZOIC ACID, POLOXAMER 407, SODIUM BENZOATE, CARAMEL.

QUESTIONS OR COMMENTS?

1-800-289-8343

LABEL COPY





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: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL	

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

Pac	kaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:42507-556-34	1000 mL in 1 BOTTLE, PLASTIC		
3.5 1 . T.C	.•		
Marketing Information			
Marketing Category	Application Number or Monograph Citatio	n Marketing Start Date	Marketing End Date
OTC monograph not final	part356	09/12/2013	

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: 9/2013 HYVEE INC