HYVEE ANTISEPTIC MINT- 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, 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 (21.6%), SORBITOL SOLUTION, FLAVOR, POLOXAMER 407, BENZOIC ACID, SODIUM SACCARIN, SODIUM BENZOATE, GREEN 3 (CI 42053).

QUESTIONS OR COMMENTS?

1-800-289-8343

LABEL COPY



	Drug Facts		
	Active ingredients Eucalyptol 0.092% Menthal 0.042% Methyl Salicylate 0.060% Thymol 0.064%	PurposeAntiplaque/Antigingivitis	
	Uses ■ To help reduce and	d prevent ■ plaque ■ gingivitis.	
	Warnings Do not use for children und	der 12 years of age.	
		Idren. If more than used for rinsing is accidentally or contact a Poison Control Center immediately.	
		trength for 30 seconds with 20 mL (2/3 fluid ounce or nd night. Do not swallow.	
	Other Information this product. Its antiseptic	Store at room temperature. Cold weather may cloud properties are not affected.	
		Water (Aqua), Alcohol (21.6%), Sorbitol Solution, zoic Acid, Sodium Saccharin, Sodium Benzoote,	
	Questions or commer	nts? 1-800-289-8343	
	ED BY HY-VEE, INC. MOINES, IA 50266	DO NOT USE IF PRINTED BAND AROUND CAP IS BROKEN OR MISSING.	
MADE	IN CANADA	TO OPEN: SQUEEZE SMOOTH AREAS ON CAP AND TURN.	7281-90
CALL 1	ION GUARANTEED -800-289-8343 .hy-vee.com	TO CLOSE: TURN CAP UNTIL IT LOCKS.	ŏ
by McNeil-PF	is not manufactured or C, Inc., owner of the re isterine® and Cool Mint	egistered IIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII	2

HYVEE ANTISEPTIC MINT

eucalyptol, menthol, methyl salicylate, thymol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42507-557
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)			
SORBITOL (UNII: 506T60A25R)			
POLOXAMER 407 (UNII: TUF2IVW3M2)			
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)			
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)			
SO DIUM BENZO ATE (UNII: OJ245FE5EU)			
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)			

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:42507-557-34	1000 mL in 1 BOTTLE, PLASTIC		
Marketing Information			
Marketing Category	Application Number or Monograph	Citation 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(42507-557)	

Revised: 9/2013 HYVEE INC.