MOUTHWASH- eucalyptol, menthol, methyl salicylate, thymol liquid
DISCOUNT DRUG MART

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.

53943-514-50 Antiseptic Mouthwash

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 (1-800-222-1222).

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 Ingreduebts

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

Caramel.

Package Principal Display Panel

MOUTHWASH

eucalyptol, menthol, methyl salicylate, thymol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53943-514
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.6 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.42 mg in 1 mL
		0.64 mg

THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.92 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARAMEL (UNII: T9D99G2B1R)	
ALCOHOL (UNII: 3K9958V90M)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
WATER (UNII: 059QF0KO0R)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53943-514-50	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	11/01/2021	

Labeler - DISCOUNT DRUG MART (047741335)

Registrant - Apollo Health and Beauty Care (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care		201901209	manufacture(53943-514)

Revised: 11/2022 DISCOUNT DRUG MART