

EAGLE MEDICATED OIL REFRESHING- menthol, methyl salicylate oil
Eagle Indo Pharma, PT

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.

Refreshing External Analgesic Oil

Active Ingredients

Menthol 14%

Methyl Salicylate 15%

Purpose

Topical Analgesic

Topical Analgesic

Uses

temporarily relieves the minor aches and pains of muscles and joints associated with
■ simple backache ■ strains ■ bruises ■ sprains

Warning

For external use only

Do not use

■ on wounds or damaged skin ■ with a heating pad

Ask a doctor before use if

you have redness over affected area

When using this product

■ avoid contact with eyes or on mucous membranes ■ do not bandage tightly

Stop use and ask a doctor if

■ condition worsens, or symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days ■ excessive skin irritation occurs

Keep out of reach of children

Keep out of reach of children To avoid accidental poisoning. If swallowed get medical help or contact a Poison Control Center right away

Directions

■ Use only as directed ■ adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily. ■ children under 2 years of age: ask a doctor

Inactive Ingredients

clove oil, eucalyptus oil, fragrance, light mineral oil

Question?

1-800-777-6717 or 1-800-645-0769

Package Label



EAGLE MEDICATED OIL REFRESHING

menthol, methyl salicylate oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60954-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	15 g in 100 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	14 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CLOVE OIL (UNII: 578389D6D0)	

LIGHT MINERAL OIL (UNII: N6K5787QVP)

EUCALYPTUS OIL (UNII: 2R04ONI662)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60954-005-24	1 in 1 BOX	06/20/2022	
1		24 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
2	NDC:60954-005-08	1 in 1 BOX	06/20/2022	
2		8 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
3	NDC:60954-005-03	1 in 1 BOX	06/20/2022	
3		3 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
4	NDC:60954-005-12	1 in 1 BOX	06/20/2022	
4		12 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/20/2022	

Labeler - Eagle Indo Pharma, PT (728682519)

Establishment

Name	Address	ID/FEI	Business Operations
Eagle Indo Pharma, PT		728682519	manufacture(60954-005)

Revised: 6/2022

Eagle Indo Pharma, PT