

EAGLE MEDICATED AROMATIC- camphor 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.

Eagle Medicated Oil Aromatic

Active Ingredients

Camphor 7%

Menthol 16%

Methyl Salicylate 35%

Purpose

Topical Analgesic

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Uses

temporarily relieves the minor aches and pains of muscles and joint 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 mucous membranes ■ do not bandage tightly

Stop use and ask a doctor if

■ condition worsens, or if 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

eucalyptus oil, spike lavender oil, light mineral oil

Question?

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

Package Label



EAGLE MEDICATED AROMATIC

camphor menthol methyl salicylate oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60954-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	7 g in 100 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	16 g in 100 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	35 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
EUCALYPTUS OIL (UNII: 2R04ONI662)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
SPIKE LAVENDER OIL (UNII: 7S2HYV1VJQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60954-007-24	1 in 1 BOX	06/20/2022	
1		24 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
2	NDC:60954-007-03	1 in 1 BOX	06/20/2022	
2		3 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
3	NDC:60954-007-08	1 in 1 BOX	06/20/2022	
3		8 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
4	NDC:60954-007-12	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	part 349	06/20/2022	

final	part 540	06/20/2022	
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Labeler - Eagle Indo Pharma, PT (728682519)

Establishment

Name	Address	ID/FEI	Business Operations
Eagle Indo Pharma, PT		728682519	manufacture(60954-007)

Revised: 6/2022

Eagle Indo Pharma, PT