

EAGLE MEDICATED- 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 Brand Medicated Oil

Active Ingredient

Menthol 14.5%
Methyl Salicylate 30.0%

Purpose

Topical Analgesic

Topical Analgesic

Uses

temporarily relieves minor muscle and joint pain due to : ■ simple backache ■ arthritis
■ strains ■ bruises
■ sprains

Warnings

For external use only

When using this product

- use only as directed
- do not get into eyes or mucous membranes
- do not apply to wound or damaged skin.
- do not bandage tightly

Stop use and ask a doctor if

- excessive skin irritation develops
- pain worsens or does not improve within 7 days, or clears up and appears again in a few days

Keep this drug out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ Adults and children 2 years and over: apply to affected area not more than 3 to 4 time daily.

■ Children under 2 years of age: ask a doctor

Inactive ingredients

D&C Yellow No. 11, D&C Green No. 6, ethyl alcohol, mineral oil, rose oil

Package Label



EAGLE MEDICATED

menthol methyl salicylate oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60954-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	14.5 g in 100 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	30 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 11 (UNII: 44F3HYL954)	
ALCOHOL (UNII: 3K9958V90M)	
MINERAL OIL (UNII: T5L8T28FGP)	
ROSE OIL (UNII: WUB68Y35M7)	
D&C GREEN NO. 6 (UNII: 4QP5U84YF7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60954-002-24	1 in 1 BOX	03/04/2022	
1		24 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
2	NDC:60954-002-36	1 in 1 BOX	03/04/2022	
2		36 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
3	NDC:60954-002-03	1 in 1 BOX	03/04/2022	
3		3 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	03/04/2022	

Labeler - Eagle Indo Pharma, PT (728682519)

Establishment

Name	Address	ID/FEI	Business Operations
Eagle Indo Pharma, PT		728682519	manufacture(60954-002)

Revised: 3/2022

Eagle Indo Pharma, PT