

EAGLE BALM- camphor menthol ointment
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 Balm Pharma

Active Ingredients

Menthol 15%

Camphor 11%

Purpose

External Analgesic

External Analgesic

Uses

For the temporary relief of minor pains and aches of muscles and joints associated with
■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains

Warnings

For External Use Only

When using this product

■ Avoid getting into the eyes or on mucous membranes ■ do not apply to wounds or damaged skin ■ do not bandage tightly or use with a heating pad ■ do not use otherwise than as directed

Stop use and ask a doctor if

■ Conditions worsens ■ symptoms persist for more than 7 days or clear up and occur again within a few days ■ redness is present

Keep out of reach of children

In case of accidental ingestion contact a doctor or Poison Control Center immediately.

Directions

■ Adults and children 12 years of age: apply to affected area not more than 3 - 4 times daily. ■ children under 12 years of age, consult a doctor before using

Other Information

■ Store in a a cool, dry place

Inactive Ingredients

fragrance, paraffin, peppermint oil, petrolatum

Package Label



EAGLE BALM

camphor menthol ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60954-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	11 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60954-010-01	1 in 1 BOX	04/15/2019	
1	NDC:60954-010-19	19.8 g in 1 JAR; 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	04/15/2019	

Labeler - Eagle Indo Pharma, PT (728682519)

Establishment

Name	Address	ID/FEI	Business Operations
Eagle Indo Pharma, PT		728682519	manufacture(60954-010)