

EAGLE GREEN 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.

Drug Facts

ACTIVE INGREDIENTS

Camphor 11%

Menthol 15%

Purpose

Analgesic

Analgesic

INDICATIONS

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

WARNING

EXTERNAL USE ONLY

- Do not apply to wounds and damaged skin
- Avoid contact with eyes
- Do not bandage tightly
- If condition worsens, or if symptoms persist for more than 7 days discontinue use and consult a doctor

Keep out of reach of children

- Keep this drug out of reach of children
- In case of accidental ingestion seek doctor or Poison Control Center

DIRECTIONS

for adults and children 2 years of age and older apply to affected area not more than 3 - 4 times daily. Children under 2 years of age consult a doctor before use

Other Information

Do not use otherwise than directed

Keep in a cool dry place

Inactive Ingredients

Vanillin, Clove Oil, petroleum Jelly, Paraffin Wax

Package Label



EAGLE GREEN BALM

camphor menthol ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60954-100
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
CLOVE OIL (UNII: 578389D6D0)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
VANILLIN (UNII: CH1530446X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60954-100-01	1 in 1 BOX	05/14/2018	
1	NDC:60954-100-20	20 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	05/14/2018	

Labeler - Eagle Indo Pharma, PT (728682519)

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