EAGLE BRAND EAGLE BALM- camphor, menthol ointment PT. EAGLE INDO PHARMA

Eagle Brand Eagle Balm

Active Ingredients

- Camphor 4%
- Menthol 15.5%

Purpose

External Analgesic

Uses

For the temporary relief of minor aches and pains 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.
- Do not use if excessive irritation of the skin develops.
- Do not use otherwise than as directed.

Stop use and ask doctor if

Condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

Keep out of reach of children

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

If pregnant or breast-feeding

Ask a health professional before use.

Directions

- 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: do not use, consult a doctor.

Other information

Store below 86°F (30°C).

Inactive ingredients

Beta carotene, D&C Green No.6, fragrance, paraffin, petrolatum

Questions?

If there are any questions or to report serious side effects, call 1-800-777-6717 or 1-800-645-0769.

Package Label

20g NDC: 60954-201-20



EAGLE BRAND EAGLE BALM

camphor, menthol ointment

	Information	

Product Type HUMAN OTC DRUG Item Code (Source) NDC:60954-201

Route of Administration TOPICAL

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
ı	CAMPHOR (SYNTHETIC) (UNII: 5TID82A1ET) (CAMPHOR (SYNTHETIC) -	CAMPHOR	4 : 100

UNII:5TJD82A1ET)	(SYNTHETIC)	4 g III 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	15.5 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
BETA CAROTENE (UNII: 01YAE03M7J)			
PARAFFIN (UNII: 1900E3H2ZE)			
PETROLATUM (UNII: 4T6H12BN9U)			
D&C GREEN NO. 6 (UNII: 4QP5U84YF7)			

Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60954-201- 20	1 in 1 BOX	12/04/2023	
1		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 Drug	M017	12/04/2023	

Labeler - PT. EAGLE INDO PHARMA (728682519)

Establishment				
Name	Address	ID/FEI	Business Operations	
PT. EAGLE INDO PHARMA		728682519	manufacture(60954-201)	

Revised: 1/2024 PT. EAGLE INDO PHARMA