GELIGA MUSCULAR BALM- menthol, methyl salicylate 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.

Geliga Muscular Balm

Active Ingredient(s)

- Menthol 13.5%
- Methyl Salicylate 29.95%

Purpose

External Analgeisc

Uses

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

Warnings

- For external use only
- Avoid getting into eyes or on mucous membranes

When using this product

- Do not apply to wounds or damaged skin.
- Do not bandage tightly.
- Do not use otherwise than as directed.

Stop use and ask a doctor if

- Condition worsens
- Symptoms persist for more than 7 days or clear up and occur again within a few days
- Pain persists for more than 10 days

If pregnant or breast-feeding

If pregnant or beast-feeding, ask a health professional before use.

Keep out of reach of children

Keep out of reach of children to avoid accidental poisoning. In case of accidental ingestion, contact a doctor or Poison Control Center immediately

Directions

- Apply liberally and gently rub on affected area.
- For adults and children 12 years and older, apply to affected area not more than 3-4 times daily.
- For children under 12 years of age, consult a doctor before using.

Other information

Store below 86 °F (30 °C).

Inactive Ingredient(s)

Fragrance, paraffin, petrolatum

Questions

Contact us at 1-800-645-0769

Package Label

20g NDC: 60954-003-20



Package Label

40g NDC: 60954-003-40



GELIGA MUSCULAR BALM

menthol, methyl salicylate ointment

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:60954-003

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of
Strength

Strength

METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: O414PZ 4LPZ)	METHYL SALICYLATE	29.95 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	13.5 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
PARAFFIN (UNII: 1900E3H2ZE)		
PETROLATUM (UNII: 4T6H12BN9U)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:60954- 003-20	1 in 1 BOX	07/03/2023		
1		20 g in 1 BOTTLE, GLASS; Type 0: Not a Combination Product			
2	NDC:60954- 003-40	1 in 1 BOX	07/03/2023		
2		40 g 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	07/03/2023	

Labeler - Eagle Indo Pharma, PT (728682519)

Establishment				
Name	Address	ID/FEI	Business Operations	
Eagle Indo Pharma, PT		728682519	manufacture(60954-003)	

Revised: 9/2023 Eagle Indo Pharma, PT