

**EAGLE BRAND MEDICATED ROLL ON- menthol, methyl salicylate oil
PT. EAGLE INDO PHARMA**

Eagle Brand Medicated Roll On

Active ingredients

- Menthol 14.5%
- Methyl Salicylate 30%

Purpose

External Analgesic

Uses

For 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 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.
- Excessive skin irritation develops.

If pregnant or breast-feeding

Ask a health professional before use.

Keep out of reach of children

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

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

Alcohol, beta carotene, D&C Green No.6, eucalyptus oil, fragrance, light mineral oil, peppermint oil, rose oil

Questions?

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

Package Label

8ml NDC: 43405-016-08



EAGLE BRAND MEDICATED ROLL ON

menthol, methyl salicylate oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60954-016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	30 g in 100 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	14.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ROSE OIL (UNII: WUB68Y35M7)	
ALCOHOL (UNII: 3K9958V90M)	
D&C GREEN NO. 6 (UNII: 4QP5U84YF7)	
BETA CAROTENE (UNII: 01YAE03M7J)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60954-016-08	1 in 1 BOX	06/24/2024	
1		8 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 Drug	M017	06/24/2024	

Labeler - PT. EAGLE INDO PHARMA (728682519)**Establishment**

Name	Address	ID/FEI	Business Operations
PT. EAGLE INDO PHARMA		728682519	manufacture(60954-016)

Revised: 6/2024

PT. EAGLE INDO PHARMA