# EAGLE BRAND MEDICATED ROLL ON REFRESH- camphor, menthol oil PT. EAGLE INDO PHARMA

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#### **Eagle Brand Medicated Roll On Refresh**

#### **Active ingredients**

- Camphor 2.2%
- Menthol 14%

#### **Purpose**

External Analgesic

#### Uses

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

#### 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 a 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 Centre 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, clove oil, D&C Red No.17, fragrance, light mineral oil, peppermint 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: 60954-012-08



### **EAGLE BRAND MEDICATED ROLL ON REFRESH**

camphor, menthol oil

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60954-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	2.2 g in 100 mL	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	14 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
D&C RED NO. 17 (UNII: ND733RX3JN)		
BETA CAROTENE (UNII: 01YAE03M7J)		
PEPPERMINT OIL (UNII: AV092KU4JH)		
CLOVE OIL (UNII: 578389D6D0)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		

ı	Packaging			
4	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60954- 012-08	1 in 1 BOX	11/01/2023	
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	11/01/2023	

# Labeler - PT. EAGLE INDO PHARMA (728682519)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
PT. EAGLE INDO PHARMA		728682519	manufacture(60954-012)		

Revised: 1/2024 PT. EAGLE INDO PHARMA