EAGLE BRAND MEDICATED OIL REFRESH- camphor, menthol oil PT. EAGLE INDO PHARMA

Eagle Brand Medicated Oil 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

24ml NDC: 60954-013-24



36ml NDC: 60954-013-36



EAGLE BRAND MED camphor, menthol oil	ICATED OIL REF	RESH			
Product Information					
Product Type	HUMAN OTC DRUG	ltem Code (Source)		NDC:60954-013	
Route of Administration	TOPICAL				
Active Ingredient/Active	Moiety				
Ingr	edient Name		Basis o Strengt	-	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)			MENTHOL		14 g in 100 mL

CAMPHOR (SYNTHETIC)

	Ingredient Name	Strength	
CLOVE OIL (UNII: 578389D6D0)			
LIGHT MINERAL OIL (UNII: N6K5787QVP)			
PEPPERMINT OIL (UNII: AV092	(U4JH)		
D&C RED NO. 17 (UNII: ND733RX3JN)			
D&C RED NO. 17 (UNII: ND733 BETA CAROTENE (UNII: 01YAE	• •		

Pa	Packaging						
#	Item Code			Marketing End Date			
1	NDC:60954- 013-24	1 in 1 BOX	11/02/2023				
1		24 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product					
2	NDC:60954- 013-36	1 in 1 BOX	11/02/2023				
2		36 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			

Labeler - PT. EAGLE INDO PHARMA (728682519)

Establishment							
Name	Address	ID/FEI	Business Operations				
PT. EAGLE INDO PHARMA		728682519	manufacture(60954-013)				

11/02/2023

Revised: 1/2024

OTC Monograph Drug M017

PT. EAGLE INDO PHARMA