EAGLE MEDICATED OIL REFRESHING- menthol, methyl salicylate oil Borden Company (Private) Limited

Refreshing External Analgesic OII

Active Ingredients

Menthol 14%

Methyl Salicylate 15%

Purpose

External Analgesic

External Analgesic

Uses

For the temporary relief of minor pains and aches 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 and damaged skin
- do not bandage tightly or use with a heating pad
- do not use otherwise that as directed

Stop use and ask a doctor if

 \blacksquare condition worsens, \blacksquare symptoms persist for more than 7 days or clear up and occur again within a few days \blacksquare redness is present

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

■ adults and children 12 years of age: apply to affected area not more than 3 to 4 times daily. ■ children under 12 years of age, consult a doctor before using

Inactive Ingredients

clove oil, eucalyptus oil, fragrance, light mineral oil

Package Label



EAGLE MEDICATED OIL REFRESHING

menthol, methyl salicylate oil

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43405-102	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: 0414PZ 4LPZ)	METHYL SALICYLATE	15 g in 100 mL	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	14 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
CLOVE OIL (UNII: 578389D6D0)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
EUCALYPTUS OIL (UNII: 2R04ONI662)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43405- 102-24	1 in 1 BOX	06/30/2021	
1		24 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
2	NDC:43405- 102-08	1 in 1 BOX	06/06/2022	
2		8 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
3	NDC:43405- 102-03	1 in 1 BOX	06/20/2022	
3		3 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
4	NDC:43405- 102-12	1 in 1 BOX	06/20/2022	
4		12 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	06/30/2021	

Labeler - Borden Company (Private) Limited (595109711)

Establishment

Name	Address	ID/FEI	Business Operations
Borden Company (Private) Limited		595109711	manufacture(43405-102)

Establishment				
Name	Address	ID/FEI	Business Operations	
Eagle Indo Pharma, PT		728682519	manufacture(43405-102)	

Revised: 10/2024 Borden Company (Private) Limited