

EAGLE MEDICATED AROMATIC- camphor menthol methyl salicylate oil
Borden Company (Private) Limited

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.

Eagle Medicated Oil Aromatic

Active Ingredients

Camphor 7%

Menthol 16%

Methyl Salicylate 35%

Purpose

External Analgesic

External Analgesic

External Analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joint associated with
■ simple backache ■ arthritis ■ strains

■ bruises ■ sprains

Warnings

■ **For external use only** ■ Avoid getting into eyes and mucous membranes

When using this product

■ do not apply to wound 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 ■ pain persists for more than 10 days ■ redness is present ■ conditions affect children under 12 years of age

Keep this drug out of reach of children

to avoid accidental poisoning. In case of accidental ingestion, contact a doctor or Poison Control Center immediately. **If pregnant or breast-feeding**, ask a health professional before use

Directions

■ adults and children 12 years of age and older apply to affected area not more than 3 to 4 time daily. ■ apply liberally and gently rub into affected area ■ children under 12 years of age, consult a doctor before using.

Inactive ingredients

eucalyptus oil, light mineral oil, spike lavender oil

Package Label



EAGLE MEDICATED AROMATIC

camphor menthol methyl salicylate oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43405-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPBOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPBOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPBOR (SYNTHETIC)	7 g in 100 mL
MENTHOL (UNII: 17T1OE1B2A) (MENTHOL (UNII: 17T1OE1B2A))	MENTHOL	16 g

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)			MENTHOL	in 100 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)			METHYL SALICYLATE	35 g in 100 mL
Inactive Ingredients				
Ingredient Name				Strength
EUCALYPTUS OIL (UNII: 2R04ONI662)				
LIGHT MINERAL OIL (UNII: N6K5787QVP)				
SPIKE LAVENDER OIL (UNII: 7S2HYV1VJQ)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43405-009-01	1 in 1 BOX	06/15/2015	
1	NDC:43405-009-24	24 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
2	NDC:43405-009-13	1 in 1 BOX	06/15/2015	
2	NDC:43405-009-03	3 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
3	NDC:43405-009-08	1 in 1 BOX	06/06/2022	
3		8 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
4	NDC:43405-009-12	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 not final		part348	06/15/2015	

Labeler - Borden Company (Private) Limited (595109711)

Establishment

Name	Address	ID/FEI	Business Operations
Borden Company (Private) Limited		595109711	manufacture(43405-009)

Establishment

Name	Address	ID/FEI	Business Operations
Eagle Indo Pharma, PT		728682519	manufacture(43405-009)

