

EAGLE MEDICATED- 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 Menthol Mthylscylte Oil

Active Ingredients

Menthol 14.5%
Methyl Salicylate 30%

Purpose

Topical Analgesic
Topical Analgesic

Uses

temporarily relieves the minor aches and pains of muscle and joints associated with :
■ simple backache ■ strains ■ bruises ■ sprains

Warnings

For external use only

When using this product

- use only as directed
- do not get into eyes or mucous membranes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs

Keep this drug out of reach of children

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

Directions

■Adults and children 2 years and over: apply to affected area not more than 3 to 4 time daily ■Children under 2 years of age: ask a doctor

Inactive ingredients

D&C Yellow No. 11, D&C Green No. 6, ethyl alcohol, mineral oil, rose oil

Package Label



EAGLE MEDICATED

menthol methyl salicylate oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43405-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	14.5 g in 100 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	30 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 11 (UNII: 44F3HYL954)	
D&C GREEN NO. 6 (UNII: 4QP5U84YF7)	
ALCOHOL (UNII: 3K9958V90M)	
MINERAL OIL (UNII: T5L8T28FGP)	
ROSE OIL (UNII: WUB68Y35M7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43405-008-01	1 in 1 BOX	05/14/2012	
1	NDC:43405-008-24	24 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
2	NDC:43405-008-02	1 in 1 BOX	05/14/2012	
2	NDC:43405-008-36	36 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
3	NDC:43405-008-13	1 in 1 BOX	05/14/2012	
3	NDC:43405-008-03	3 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
4	NDC:43405-008-08	1 in 1 BOX	06/27/2022	
4		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 not final	part348	05/14/2012	

Labeler - Borden Company (Private) Limited (595109711)

Establishment

Name	Address	ID/FEI	Business Operations
Borden Company (Private) Limited		595109711	manufacture(43405-008)

Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

Eagle Indo Pharma

728682519

manufacture(43405-008)

Revised: 7/2022

Borden Company (Private) Limited