

EAGLE MEDICATED- menthol methyl salicylate oil
Eagle Indo Pharma

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 Mthylsclyte 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

Warning

For external use only

Do not use

■ on wounds or damaged skin ■ with a heating pad

Ask a doctor before use if

you have redness over affected area

When using this product

■ avoid contact with eyes or mucous membranes ■ 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 out of reach of children

Keep out of reach of children To avoid accidental poisoning. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ Use only as directed ■ 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

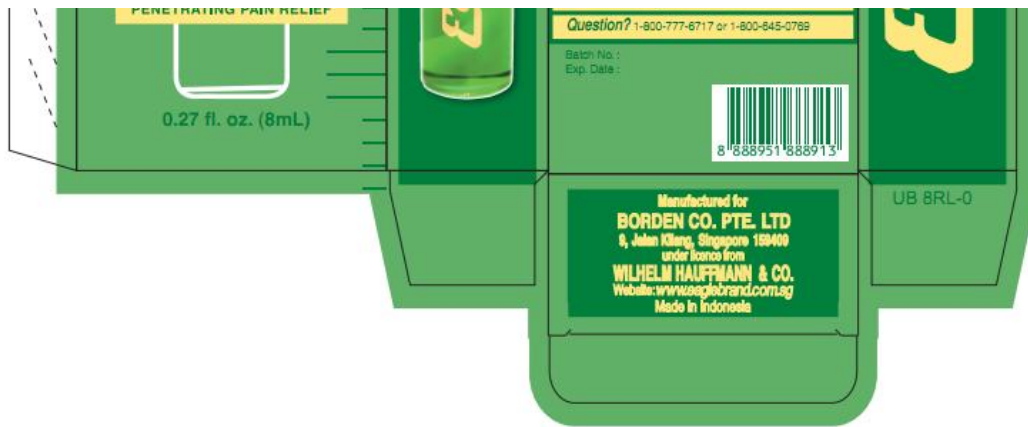
D&C Green No. 6, D&C Yellow No. 11, ethyl alcohol, mineral oil, rose oil

Question?

1-800-777-6717 or 1-800-645-0769

Package Label





EAGLE MEDICATED

menthol methyl salicylate oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60954-008
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:60954-008-24	1 in 1 BOX	06/27/2022	
1		24 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
2	NDC:60954-008-36	1 in 1 BOX	06/27/2022	
2		36 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
3	NDC:60954-008-03	1 in 1 BOX	06/27/2022	
3		3 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
4	NDC:60954-008-08	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	06/20/2012	

Labeler - Eagle Indo Pharma (728682519)

Establishment

Name	Address	ID/FEI	Business Operations
Eagle Indo Pharma		728682519	manufacture(60954-008)

Revised: 7/2022

Eagle Indo Pharma