

MUSCULAR BALM- capsaicin menthol methyl salicylate ointment

Eagle Indo Pharma, PT

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.

Drug Facts

Active Ingredients

Capsaicin 0.15%

Menthol 13.5%

Methyl Salicylate 30%

Purpose

External Analgesic

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**

■ Avoid getting into the eyes or on mucus membranes.

When using this product

■ do not apply to wound or damaged skin ■ do not bandage tightly ■ do not use if excessive irritation of the skin develops

■ 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 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 and over: Apply to affected area not more than 3 to 4 time daily ■
- Children under 12 years of age:consult a doctor

Inactive Ingredients

eucalyptol, fragrance, paraffin wax and petroleum jelly

Package Label



capsaicin menthol methyl salicylate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60954-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.15 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	13.5 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	30 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
EUCALYPTOL (UNII: RV6J6604TK)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60954-001-01	1 in 1 BOX	05/14/2010	
1	NDC:60954-001-20	20 g in 1 JAR; 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	05/14/2010	

Labeler - Eagle Indo Pharma, PT (728682519)

Establishment

Name	Address	ID/FEI	Business Operations
Eagle Indo Pharma, PT		728682519	manufacture(60954-001)

Revised: 5/2019

Eagle Indo Pharma, PT