ATOMIC BALM- methyl salicylate, capsaicin ointment Performance Health, LLC

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.

Atomic Balm Ointment

Drug Facts

Active Ingredients

Methyl Salicylate 12.5% Capsaicin 0.025%

Purpose

Counterirritant

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with strains, sprains, bruises, simple backache, and arthritis. Combined with stretching and calisthenics, Atomic Balm assists in the warm-up process, especially in cool, damp weather. Do not bandage tightly.

Warnings

For external use only.

Use only as directed. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Do not apply to wounds or damaged skin. Avoid contact with the eyes. If condition worsens, or if the symptoms persist for more than 7 days, or clear up and occur again within a few days, discontinue use and consult a doctor. Consult a doctor before administering to children, including teenagers, with chicken pox or flu.

Keep this and all drugs out of the reach of children

to avoid accidental poisoning.

Directions

Gently massage into painful area. Adults and children 6 years of age and older: apply to affected area not more than 3 - 4 times daily. Children under 6 years of age: consult a doctor. To apply: spread 1/8 " layer of Atomic Balm over area. Do not bandage tightly.

Other information

This product will cause mild skin irritation. Discontinue use if excessive irritation of skin develops. Use with caution on sensitive skin. Store in a cool, dry place with cap closed tightly.

Inactive Ingredients

Lanolin, Paraffin, Petrolatum

Questions?

(800) 345-2231

Package Labeling:





Drug Facts

ATOMIC BAI

ANALGESIC OINTMENT MEDIUM

ATOMIC BALM

methyl salicylate, capsaicin ointment

Product Information	
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:59316-999

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: O414PZ4LPZ)	METHYL SALICYLATE	12.5 g in 100 g		
CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM)	CAPSAICIN	0.025 g in 100 g		

Inactive Ingredients				
Ingredient Name	Strength			
LANOLIN (UNII: 7EV65EAW6H)				
PARAFFIN (UNII: 1900E3H2ZE)				
PETROLATUM (UNII: 4T6H12BN9U)				

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:59316-999- 21	78 g in 1 TUBE; Type 0: Not a Combination Product	05/19/2017	12/31/2024		
2	NDC:59316-999- 96	454 g in 1 JAR; Type 0: Not a Combination Product	05/19/2017	12/31/2024		
3	NDC:59316-999- 97	2268 g in 1 JAR; Type 0: Not a Combination Product	05/19/2017	12/31/2024		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part348	05/19/2017	12/31/2024			

Labeler - Performance Health, LLC (794324061)

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