JOINT AND MUSCLE PAIN - menthol cream BioZone Laboratories, Inc.

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

Menthol (5%)

Topical Analgesic

Directions

Provides penetrating temporary relief for minor pain in muscles and joints associated with:

- Backache
- Arthritis
- Bruises
- Sprains

Warnings

- **For external use only.** Do not use with a heating pad. Do not apply to wounds or damaged skin. Do not bandage tightly after use.
- Avoid contact with eyes.
- Discontinue use and consult a physician if condition worsens, or if symptoms persist more than 7 days, or clear up and occur again within a few days.
- **Keep out of reach of children.** if swallowed, get medical help or contact a poison control center right away.

Directions

- **Adults and children over the age of 2:** Apply generously to affected area. Massage well into painful area. Repeat as necessary, but not more than 3 to 4 times daily.
- **Children under the age of 2:** Do not use; consult a physician.

Inactive Ingredients

Water, Butylene Glycol, *Prunus amygdalus dulcis* (Sweet Almond) Oil, PEG-12 Glyceryl Distearate, Cetyl Alcohol, Glyceryl Stearate, Cyclomethicone, PEG-100 Stearate, Dimethicone, *Aloe barbadensis* Leaf Extract, Ehtylhexylglycerin, Carbomer, Caprylyl Glycol, Hexylene Glycol, Phenoxyethanol, Triethanolamine, Xanthan Gum.

Image: tube_shk10_1.jpg



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Purpose

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Distributed by Shaklee Corporation 4747 Willow Road, Pleasanton, CA 94588





PT518A Item #31051

JOINT AND MUSCLE PAIN

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:55379-404

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

Menthol (UNII: L7T10 EIP3	A) (Menthol - UNII:L7T10EIP3A)		Menthol		50 mg in 1 g				
Packaging									
# Item Code	Package Description	Marketing	g Start Date	Ma	rketing End Date				
1 NDC:55379-404-85	85 g in 1 TUBE								
Marketing Information									
Marketing Category	Application Number or Monograph Citation		Marketing Start Date		Marketing End Date				
OTC monograph not final	part348		07/15/2009						

Labeler - BioZone Laboratories, Inc. (555564293)

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