ARTHRI-SUPPORT - menthol cream Pure Science International, 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

Active Ingredients

Menthol 5%

Purpose

Menthol 5%......Topical Analgesic

Uses

For temporary relief of minor aches and pains associated with arthritis, backaches, sprains, bruises, strains, and stiffness.

Warnings

- For external use only.
- Use only as directed.
- Avoid contact with eyes and mucous membranes.

Do not apply to open wounds or damaged skin.

KEEP OUT OF REACH OF CHILDREN

 if swallowed get medical help or contact a poison center right away.
Do not bandage tightly or use with heating pads.

Consult a physician before use for children under 12 or if; pregnant or nursing; condition persists more than seven days or clears up and returns within seven days; excessive skin irritation occurs; you are prone to allergic reactions to salicylates, including aspirin.

Directions

- Adults and children under 12 years of age and older: apply to affected area no more than 3 to 4 times daily.
- Children under 12: consult a physician.
- Apply generously and massage into affected areas until completely absorbed.
- Apply before and after sports or exercise to help soothe aching muscles, muscle strain, and stiffness.

Repeat as needed up to four times a day.

Other Information

Store at 20° to 25° C (68° to 77° F)

Inactive Ingredients

Water, Methyl Glucose Sesquistearate, Arthri-Support Cream Proprietary Herbal Extract Blend, Natural Oil of Wintergreen (Gaultheria procumbens), Avocado Oil (Persea gratissima), Stearic Acid, Aloe (Aloe barbadensis), Grape Seed Oil (Vitis vinifera), Cyclomethicone, Shea Butter (Butyrospermum parkii). Steareth-10, Phenoxyethanol Methylparaben, Ceteareth-20, Steareth-2.

Questions/comments?

714-639-0343 Manufactured for: Pure Science Int., Mission Viejo, CA 92692

Principal Display Panel

PURE SCIENCE INTERNATIONAL

ARTHRI SUPPORT

FAST AND LASTING PAIN REFLIEF!

Supports Joint and Muscle Comfort

MEDICATED CREAM net weight 3.0 oz. (85g)



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ARTHRI-SUPPORT

menthol cream

Product Information

Product Type HUMAN OTC DRUG NDC:43078-001 Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	5 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GAULTHERIA PRO CUMBENS TOP (UNII: 830295X963)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GRAPE SEED OIL (UNII: 930 MLC8 XGG)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
SHEA BUTTER (UNII: K49 155WL9 Y)	
STEARETH-10 (UNII: FD0913P475)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A218 C7HI9 T)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
STEARETH-2 (UNII: V56DFE46J5)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:43078-001-30	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	12/01/2007		

Labeler - Pure Science International, Inc. (078532055)

Establishment			
Name	Address	ID/FEI	Business Operations
Pure Source, Inc.		969241041	manufacture (430 78 - 001)

Revised: 12/2013 Pure Science International, Inc.