ARTHRITIS HOT- menthol and methyl salicylate cream Chattem, 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.

Arthritis Hot

Drug Facts

Active ingredients

Menthol 10%

Methyl salicylate 15%

Purpose

Topical analgesic

Uses

temporarily relieves minor pain associated with:

- arthritis
- simple backache
- muscle strains
- sprains
- bruises
- cramps

Warnings

For external use only

Allergy alert: If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

When using this product

- use only as directed
- do not bandage tightly or use with a heating pad
- avoid contact with eyes or mucous membranes
- do not apply to wounds or damaged, broken or irritated skin

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness is present
- irritation develops

If pregnant or breast-feeding,

ask a health care professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children over 12 years:

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but no more than 3 to 4 times daily

children 12 years or younger: ask a doctor

Inactive ingredients

carbomer, cetyl esters, diisopropyl adipate, emulsifying wax, oleth-3 phosphate, stearic acid, triethanolamine, water (283-085)

PRINCIPAL DISPLAY PANEL

ARTHRITIS HOT deep penetrating Pain Relief Crème NET WT 3 OZ (85g)



ARTHRITIS HOT

menthol and methyl salicylate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0600
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	15 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
CETYL ESTERS WAX (UNII: D072FFP9GU)		
DIISOPROPYL ADIPATE (UNII: P7E6 YFV72X)		
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
WATER (UNII: 059QF0KO0R)		

	Packaging					
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
l	1 NDC:41167-0600-3	1 in 1 CARTON	12/0 1/19 9 8			
l	1	85 g in 1 TUBE; 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	12/01/1998		

Labeler - Chattem, Inc. (003336013)

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