

CARE ONE COOL HEAT PAIN RELIEVING - menthol, methyl salicylate cream
AMERICAN SALES COMPANY

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	Purpose
Menthol 10%.....	Topical Analgesic
Methyl Salicylate 30%.....	Topical Analgesic

Uses

temporarily relieves minor pain associated with

- Arthritis
- Simple backache
- Muscle strains
- Sprains
- Bruises
- Cramps

Warning

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, 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 professional before use.

Keep out of reach of children. In case of accidental ingestion, 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 4 times daily
- close cap tightly after use
- keep carton as it contains important information

Children 12 years or younger: Ask a doctor

Inactive ingredients

Carbomer, Cetyl Esters, Emulsifying Wax, Oleth-3 phosphate, Stearic Acid, Triethanolamine, Water

DISTRIBUTED BY: AMERICAN SALES COMPANY

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www.care1.info

Made in Korea



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CARE ONE COOL HEAT PAIN RELIEVING

menthol, methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-863
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) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	30 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ESTERS WAX (UNII: D072FFP9GU)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-863-35	1 in 1 CARTON		
1		35 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/01/2012	

Labeler - AMERICAN SALES COMPANY (809183973)

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