CONTROL MENSTRUAL CRAMP RELIEF- menthol cream
Cosmetic Specialty Labs, 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.

Active Incredient

Menthol, 3.0%

Purpose

Topical analgesic

Uses

temporarily relieves minor pain associated with: • arthritis • simple backache • muscle strains • sprains • bruises • cramps

Warnings

for external use only

When using this prodcut• use only as directed • avoid contact with eyes or mucous membranes • do not apply to wounds or damaged 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 develeps

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.

Directions:

Adults and children over 12 years:• apply to affected area • massage into painful area until throughly absorbed into skin • repeat as necessary, but no more than 4 time daily

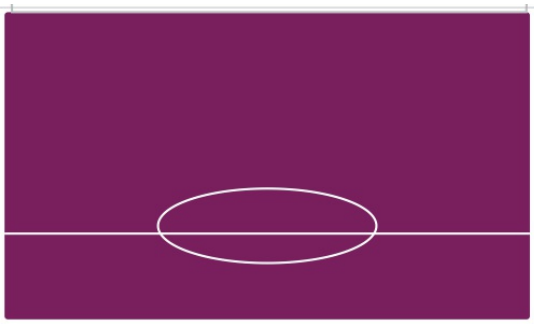
Children 12 years or younger: ask a doctor

Inactive ingredients

Butylene Glycol, Caprylyl Glycol, Carbomer, Cetyl Alcohol, Chamomilla recutita (Matricaria) Flower Extract, Citrus aurantium Dulcis (Sweet Orange) Peel Oil, Cocos nucifera

(Coconut) Oil, Creatine, Dimethicone, Eucalyptus globulus Leaf Oil, Fragrance, Glyceryl Stearate, Laureth-4, Phenoxyethanol, Purified Water, Salvia officinalis (Sage) Extract, Stearic Acid, Triethanolamine.

Package Label



Pantone 249c

CONTROL MENSTRUAL CRAMP RELIEF

menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58133-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHAMOMILE (UNII: FGL3685T2X)	
ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)	
COCONUT OIL (UNII: Q9L0O73W7L)	
LAURETH-4 (UNII: 6HQ855798J)	
SAGE (UNII: 065C5D077J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
CREATINE (UNII: MU72812GK0)	
DIMETHICONE 200 (UNII: RGS4T2AS00)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-010-03	89 mL in 1 TUBE; Type 0: Not a Combination Product	03/04/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/04/2021	

Labeler - Cosmetic Specialty Labs, Inc. (032973000)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty Labs, Inc.		032973000	manufacture(58133-010) , pack(58133-010) , label(58133-010) , analysis(58133-010)

Revised: 8/2021 Cosmetic Specialty Labs, Inc.