

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.

KRT packet

Active Ingredient

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 product 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 develops

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

Package label

EYEMARK LANE
NO PRINT AREA

Drug Facts: Active ingredient: Menthol 3%
Inactive ingredients: Butylene Glycol, Caprylyl Glycol, Carbomer, Cetyl Alcohol, Chamomilla recutita (Matricaria) Flower Extract, Citrus sinensis (Sweet Orange) Peel Oil, Cocos nucifera (Coconut) Oil, Creatine Monohydrate, Dimethicone, Eucalyptus globulus Leaf Oil, Fragrance, Glycerol Stearate, Laureth-4, Phenoxethanol, Purified Water, Salvia officinalis (Sage) Extract, Sodium Laureth Sulfate, Stearic Acid, Triethanolamine.
Directions: Adults and children over 12 years old - apply to affected area, massage into painful area until thoroughly absorbed into skin, repeat as necessary but no more than 4 times daily. Children 12 years or younger consult with a doctor.
For best results apply a liberal amount.
Uses: Temporarily relieves minor pain associated with; cramps, muscle strains, simple backache; sprains, bruises and arthritis.
Warning: For external use only.
When using this product: 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 develops.
Keep Out Of Reach Of Children: If swallowed get medical help or contact a Poison Control Center right away. If Pregnant Or Breast Feeding Ask a health professional before use.
Manufactured Exclusively For: KR Technologies, LLC
Norman OK 73072
Made in the USA
Never Animal Tested
NDC#58133-010-01



CONTROL MENSTRUAL CRAMP CREAM
HORMONE FREE • ALL NATURAL FORMULA
WWW.CONTROLCRAMPS.COM
SAMPLE ONLY NOT FOR RESALE
NWT#C-0.26 FL OZ / 7.5 ML



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)	
WATER (UNII: 059QF0KO0R)	
CHAMOMILE (UNII: FGL3685T2X)	
ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)	
COCONUT OIL (UNII: Q9L0O73W7L)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
LAURETH-4 (UNII: 6HQ855798J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
SAGE OIL (UNII: U27K0H1H2O)	
CREATINE MONOHYDRATE (UNII: 9603LN7R2Q)	
TROLAMINE (UNII: 9O3K93S3TK)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
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:58133-010-01	7.5 mL in 1 PACKET; Type 0: Not a Combination Product	05/24/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/24/2023	

Labeler - Cosmetic Specialty Labs, Inc. (032973000)

Establishment

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

Revised: 5/2023

Cosmetic Specialty Labs, Inc.