## 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.

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#### 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 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

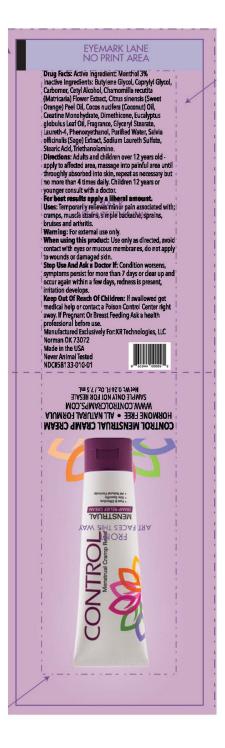
Adults and children over 12 years: • apply to affected area • massage into painful area until throughly absorbed into skin • repeat as necessary, but no more than 4 time daily

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 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



menthol cream									
Product Inform	nation								
Product Type		HUMAN OTC DRUG	Item	Code (Source)	NDC:58133-010				
Route of Administ	tration	TOPICAL							
Noute of Administ		TOTTOTL							
Active Ingredie	Active Ingredient/Active Moiety								
	Ingredie	nt Name		Basis of Strengt	th Strength				
MENTHOL (UNII: L7T	-		P3A)	MENTHOL	3 g in 100 mL				
Inactive Ingred	ients								
		Ingredient Na	ne		Strength				
PHENOXYETHANOL	(UNII: HIE492Z	Z 3T)							
WATER (UNII: 059QFC	)KO0R)								
CHAMOMILE (UNII: F	GL3685T2X)								
ORANGE OIL, COLD	ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)								
COCONUT OIL (UNII:	Q9L0073W7L)								
BUTYLENE GLYCOL									
CAPRYLYL GLYCOL									
CETYL ALCOHOL (UI		1)							
LAURETH-4 (UNII: 6H	-								
STEARIC ACID (UNII:									
GLYCERYL STEARAT		Z 5MH785I)							
SAGE OIL (UNII: U27k									
CREATINE MONOHY		9603LN7R2Q)							
TROLAMINE (UNII: 90									
DIMETHICONE (UNII:									
EUCALYPTUS OIL (U									
SODIUM LAURETH S									
CARBOMER 940 (UN	II: 4Q93RCW27	E)							
Product Charac	teristics								
Color		white	Score						
Shape			Size						
Flavor		Imprint Co		le					
Contains	Contains								
Packaging									
# Item Code	Code Package Description		on	Marketing Start Date	Marketing End Date				
	.5 mL in 1 PAC roduct	KET; Type 0: Not a	Combination	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	<b>Business Operations</b>
Cosmetic Specialty Labs, Inc.		032973000	manufacture(58133-010)

Revised: 5/2023

Cosmetic Specialty Labs, Inc.