# KRT HEAT MUSCLE ENDURANCE CREAM- 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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#### **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 sinensis (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, Stearic Acid, Triethanolamine.

# **Package Label**





Patent Pending • Made in the USA NEVER ANIMAL TESTED • PLEASE RECYCLE





Norman, OK 73072 Toll Free Phone 1(855) 307-0990 3839039

# KRT HEAT MUSCLE ENDURANCE CREAM

menthol cream

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:58133-750

**Route of Administration** TOPICAL

# Active Ingredient/Active Moiety Ingredient Name Basis of 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)		
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ)		
CITRUS SINENSIS FRUIT OIL (UNII: WV48LBL15Q)		
COCONUT OIL (UNII: Q9L0O73W7L)		
<b>LAURETH-4</b> (UNII: 6HQ855798J)		
SALVIA OFFICINALIS FLOWERING TOP (UNII: 48JCS720FN)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TROLAMINE (UNII: 903K93S3TK)		
CREATINE MONOHYDRATE (UNII: 9603LN7R2Q)		
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:58133-750- 03	89 mL in 1 TUBE; Type 0: Not a Combination Product 03/04/2021				

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
part348	03/04/2021			
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date		

# Labeler - Cosmetic Specialty Labs, Inc. (032973000)

Establishment			
Name	Address	ID/FEI	Business Operations
Cosmetic Specialty Labs, Inc.		032973000	$manufacture (58133-750) \; , \; pack (58133-750) \; , \; label (58133-750) \; , \\ analysis (58133-750) \; .$

Revised: 8/2021 Cosmetic Specialty Labs, Inc.