

RED LION 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 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
- do not bandage tightly or use with heating pad
- avoid contact with the 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 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 the skin
- repeat as necessary, no more than 4 times daily

Children 12 years or younger

ask a doctor

INACTIVE INGREDIENTS

Aloe Barbadensis Leaf, Arnica Montana Flower Extract, Butylene Glycol, Caprylyl Glycol, Carbomer, Cetearyl Alcohol, Cetyl Alcohol, Citrus Aurantium Dulcis (Orange) Peel Oil, Cymbopogon Martinii (Palmarosa) Oil, Eucalyptus Globulus Leaf Oil, Hamamelis Virginiana (Witch Hazel) Bark / Leaf / Twig Extract, Lavandula Angustifolia (Lavender) Oil, Mentha Piperita (Peppermint) Leaf Oil, Methylsulfonylmethane, Phenoxyethanol, Purified Water, Salix Alba (Willow) Bark Extract, Sorbitol, Tocopheryl Acetate, Triethanolamine.

PRINCIPAL DISPLAY PANEL

KATHY DALLAS® **Ultra**



**RED LION
RELIEF
CREAM®**

**WITH MSM
& ALOE VERA**

Sports Rub
for after Strenuous
Exercise or Exertion

Maximum Comfort
for Joints & Muscles

NON STAINING

Net Wt. 4 fl oz (120 mL)
Made in USA

Drug Facts

Active Ingredient	Purpose
Menthol 3.0%	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 ■ do not bandage tightly or use with heating pad ■ 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 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

children 12 years or younger: ask a doctor

Inactive ingredients Aloe Barbadosensis Leaf, Anthemis Nobilis, Arnica Montana Flower Extract, Calendula Officinalis, Capsicum Frutescens Resin, Caprylyl Glycol, Carbomer, Coriandrum Sativum (Coriander) Fruit Oil, Diazolidinyl Urea, Fragrance, Helianthus Annuus (Sunflower) Seed Oil, Hypericum Perforatum, Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, Matricaria Chamomilla, Methylsulfonylmethane, Phenoxyethanol, Purified Water, Salix Alba (Willow) Bark Extract, Sodium Lauryl Sulfate, Sorbitol, Triethanolamine.

Manufactured Exclusively For
Kathy Dallas Cosmetics
Houston, Texas 77069

7598156

RED LION RELIEF

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58 133-075
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 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
1,3-BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ORANGE OIL (UNII: AKN3KSD11B)	
PALMAROSA OIL (UNII: 0J3G3O53ST)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0K00R)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
SORBITOL (UNII: 506T60A25R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-075-04	115 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/01/2012	

Labeler - Cosmetic Specialty labs, Inc. (032973000)**Establishment**

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty labs, Inc.		032973000	manufacture(58133-075)

