EMU THERAPY COOL MENTHOL THERAPY PAIN RELIEF CREAMmenthol cream ACA MANAGEMENT LLC

EMU THERAPY Cool Menthol Therapy Pain Relief Cream

Active Ingredient:

Menthol, USP (2.75%)

Purpose:

Topical Analgesic

Uses:

Temporary relief of minor aches and pains associated with arthritis, simple backache, strains, sprains, and bruises.

Warnings:

For external use only.

Do not use

on wounded, damaged or irritated skin.

When using this product

avoid contact with eyes or mucous membranes, do not bandage tightly.

Stop use and ask a doctor

• if you experience a rash and/or a reaction, condition worsens, or if symptoms persist for more than 10 days or clear up and occur again within a few days.

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:

• For adults and children 2 years of age and older: apply to affected area not more than 3 or 4 times a day. Consult a doctor before using for children under 2 years of age.

Inactive Ingredients:

Aloe Barbadensis leaf (Aloe Vera Gel) Juice, Anthemis Nobilis (Roman Chamomile) Oil, Aqua (Deionized water), Arnica Montana Flower Extract, Ascorbyl Palmitate (Vitamin C), Calendula Officinalis Extract, Capsaicin, Carbomer, Centaurea Cyanus (Cornflower) Extract, Chamomilla Matricaria (Chamomile) Extract, Coriandrum Sativum (Coriander) Oil, Emu Oil, Ethylhexylglycerin, FD&C Blue #1; FD&C Yellow #5, Glycerin, Hamamelis Virginiana (Witch Hazel), Helianthus Annuus (Sunflower) Oil, Hypericum Perforatum (St. John's Wort), Lamium Album (White Nettle) Extract, Methylsulfonylmethane (MSM), Parfum (Fragrance), Phenoxyethanol, Salix Alba (Willow) Bark Extract, SD-Alohol 40B, Sodium Lauryl Sulfate, Sorbitol, Tanacetum Parthenium (Feverfew) Extract, Tilla Cordata (Linden) Bark Extract, Triethanolamine.

Questions or Comments?

1-800-222-0554 or www.coolmentholTheropyPainCream.com

Package Labeling:



EMU THERAPY COOL MENTHOL THERAPY PAIN RELIEF CREAM

menthol cream

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:83591-416

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)

MENTHOL

27.5 mg in 1 mL

Inactive Ingredients Ingredient Name Strength ALOE VERA LEAF (UNII: ZY81Z83H0X)

WATER (UNII: 059QF0KO0R)

ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)

ASCORBYL PALMITATE (UNII: QN83US2B0N)

CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)

CAPSAICIN (UNII: S07044R1ZM)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CHAMOMILE (UNII: FGL3685T2X)	
CORIANDER (UNII: 10V56052IK)	
EMU OIL (UNII: 344821WD61)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCERIN (UNII: PDC6A3C0OX)	
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS)	
HYPERICUM PERFORATUM WHOLE (UNII: XK4IUX8MNB)	
LAMIUM ALBUM WHOLE (UNII: 046Y1357I6)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SORBITOL (UNII: 506T60A25R)	
FEVERFEW (UNII: Z64FK7P217)	
TROLAMINE (UNII: 903K93S3TK)	

l	Packaging								
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
	1	NDC:83591-416- 00	237 mL in 1 JAR; Type 0: Not a Combination Product	08/08/2023					

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC Monograph Drug	M017	08/08/2023					

Labeler - ACA MANAGEMENT LLC (119034214)

Revised: 11/2023 ACA MANAGEMENT LLC