EMU THERAPY RED HOT PEPPER PAIN RELIEF CREAM- menthol, capsaicin cream ACA MANAGEMENT LLC

EMU THERAPY Red Hot Pepper Pain Relief Cream

Active Ingredient:

Menthol, USP (2.75%)

Capsaicin (0.025%)

Purpose:

Topical Analgesic

Uses:

Temporary relief of minor aches and pains of muscles and joints.

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:

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, 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, Centaurea Cyanus (Corniflower) Extract, Chamomilla Recutita (Chamomile) Extract, Coriandrum Sativum (Coriander) Oil, Emu Oil, Ethylhexylglycerin, Hamamelis Virginiana (Witch Hazel), Helianthus Annuus (Sunflower) Oil, Hypericum Perforatum (St. John's Wort), Lamium Album (White Nettle) Extract, Methylsulfonyl Methane (MSM), Parfum (Fragrance), Phenoxyethanol, Salix Alba (Willow) Bark Extract, SD-Alcohol 40B, Sodium Lauryl Sulfate, Sorbitol, Tillia Cordata (Linden) Bark Extract, Triethanolamine, Fever Few Extract, FD&C Blue #1, FD&C Yellow #5.

Questions or Comments?

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

Package Labeling:



EMU THERAPY RED HOT PEPPER PAIN RELIEF CREAM

menthol, capsaicin cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83591-417
Route of Administration	TOPICAL		

active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	15 mg in 1 mL
CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM)	CAPSAICIN	0.25 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)	
CHAMOMILE (UNII: FGL3685T2X)	
CORIANDER (UNII: 10V56052IK)	
EMU OIL (UNII: 344821WD61)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
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)	
TROLAMINE (UNII: 903K93S3TK)	
TANACETUM PARTHENIUM WHOLE (UNII: 6GE7Z0761K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83591-417- 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