PROFESSIONAL THERAPY MUSCLECARE PRO- menthol and camphor cream ACTIVE AND INNOVATIVE, LLC

ACTIVE AND INNOVATIVE (as PLD) - MUSCLECARE OINTMENT (70039-303)

Active Ingredient (% by weight)

Camphor 4.0% Menthol 4.0%

Purpose

Analgesic (pain relief)

Uses:

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, sprains, bruises.

Warnings:

For external use only.

- Caution: Discontinue use if excessive irritation of the skin develops. Avoid getting into eyes or on mucous membranes.
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.
- Do not apply to wounds or damaged skin. Do not bandage tightly.

Keep out of reach of children. Flammable: Keep away from fire and flame.

- Use only as directed
- Do not use if pregnant or breastfeeding
- If swallowed, get medical help or contact a Poison Control center right away

Directions:

Adults and children 12 years of age or older: Rub this soothing cream on the affected area not more than 3 to 4 times daily. Children under the age of 12: Do not use, consult a doctor.

Other Information:

Store under normal storage conditions. Store away from children.

Inactive Ingredients:

Acacia Senegal Gum, Aloe Barbadensis Leaf Juice, Carthamus Tinctorius (Safflower) Oleosomes, Cetearyl Alcohol, Cetyl Alcohol, Chondroitin Sulfate, D-Glucosamine Sulfate Potassium, Dimethyl Sulfone (MSM), Ethylhexylglycerin, Eucalyptus Globulus Leaf/Twig Oil, Gaultheria Procumbens (Wintergreen) Leaf Oil, Glycerin, Magnesium Chloride, Phenoxyethanol, Polysorbate 60, Thymol, Tocopherol, Urea, Vitis Vinifera (Grape) Seed Oil, Water, Xanthan Gum



PROFESSIONAL THERAPY MUSCLECARE PRO

menthol and camphor cream

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:70		NDC:700	39-303
Route of Administration	TOPICAL				
Active Ingredient/Active	Moiety				
Ing	redient Name		Basis Stren		Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)			CAMPHOR (SYNTHETIC)		4 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MEN	ITHOL - UNII:L7T10EIP3A)		MENTHOL		4 g in 100 g
Inactive Ingredients					
	Ingredient Name			:	Strength
ACACIA (UNII: 5C5403N26O)					
ALOE VERA LEAF (UNII: ZY81Z83	HOX)				
CARTHAMUS TINCTORIUS (SAFF	LOWER) OLEOSOMES (U	NII: 9S60Q72309)			

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)

CETYL ALCOHOL (UNII: 936JST6JCN)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
GLUCOSAMINE SULFATE POTASSIUM CHLORIDE (UNII: 15VQ11I66N)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
THYMOL (UNII: 3J50XA376E)	
TOCOPHEROL (UNII: R0ZB2556P8)	
UREA (UNII: 8W8T17847W)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
COPHEROL (UNII: R0Z B2556P8) EA (UNII: 8W8T17847W) APE SEED OIL (UNII: 930MLC8XGG) ATER (UNII: 059QF0K00R)	

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70039- 303-32	906 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/03/2024	
2	NDC:70039- 303-04	115 g in 1 TUBE; Type 0: Not a Combination Product	05/03/2024	
3	NDC:70039- 303-16	453 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/03/2024	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M017	05/03/2024	

Labeler - ACTIVE AND INNOVATIVE, LLC (206978079)

Registrant - MCKENNA LABS, INC. (090631412)

Establishment					
Name	Address	ID/FEI	Business Operations		
MCKENNA LABS, INC.		090631412	manufacture(70039-303)		

Revised: 5/2024

ACTIVE AND INNOVATIVE, LLC