ACHY- menthol cream cream Kelada Creative Group LLC DBA SALVE

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.

Achy external analgesic

Menthol 1.5%

Temporarily relieves the minor aches and pains associated with tendonitis, backache, leg cramps, sore muscles, arthritis, bruises, sprains, and swelling.

Warnings

For external use only.

Do not use other than directed

When using this product

- avoid contact with eyes and mucous membranes
- do not apply tp wounds or broken skin

Stop use and ask a doctor if

- excessive skin irritation develops
- condition worsens

Adults and children 3 years of age and older liberally massage to affected are not more than 4 times daily

Children under 3 years of age ask a doctor before using

Organic extra virgin olive oil, organic comfrey oil, organic arnica oil, beeswax, Indian lemongrass essential oil, French clary sage essential oil, Spanish rosemary essential oil, and Natural Vitamin E

Keep out of reach of children. If swallowed get medical help or contact Poison Control Center right away (1-800-222-1222

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Purpose

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Drug Facts Active ingredients





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GLUTEN

hand crafted

Based on natural medicine. 100% NATURAL



@SalveNaturals

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certified

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eall natural and organic skin care

PAIN RELIEF NATURAL

arthritis | bruises | sprains Leg cramps I sore musches tendinitis | backache

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Houston, Texas

Topical analgesic

Uses

Temporarily relieves the minor aches and pains associated with

- - backache leg cramps sore muscles

- arthritis
- bruises
- sprains
- swelling

Warnings

For external use only

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■ excessive skin irritation develops
■ condition worsens

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

- adults & children 3 years of age and older; liberally massage to affected area not more than 4 times daily
- children under 3 years of age: ask a doctor

Other information store at less than 25°C (77°F) with lid closed tightly

Inactive ingredients Olea europaea (Organic Extra Virgin Olive) Oil, Symphylum officinale (Organic Comfrey) Oil, Arnica montana (Organic Arnica) Oil, Beeswax, Cymbopogon citratus (Indian Lemongrass) Essential Oil, Salvia sclarea (French Clary Sage) Essential Oil, Rosmarinus officinalis (Spanish Rosemary) Essential Oil, Tocopherol (Natural Vitamin E).

(Questions or comments? 1-281-684-0755 salvenaturals.com

NO Artificial fragrance

NO Aluminum NO Petrochemicals NO Artificial dyes

Phthalates

ACHY

menthol cream cream

Product Information

HUMAN OTC DRUG NDC:71157-0017 Product Type Item Code (Source)

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	28 g in 90 mL

Inactive Ingredients

Ingredient Name	Strength
OLIVE OIL (UNII: 6UYK2W1W1E)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
COMFREY LEAF (UNII: DG4F8T839X)	
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
WHITE WAX (UNII: 7G1J5DA97F)	
CLARY SAGE OIL (UNII: 87L0D4U3M0)	
.ALPHATO COPHEROL (UNII: H4N855PNZ1)	

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71157-0017-1	90 mL in 1 CAN; Type 0: Not a Combination Product	12/19/2016	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	12/19/2016		

Labeler - Kelada Creative Group LLC DBA SALVE (014340121)

Registrant - Kelada Creative Group LLC DBA SALVE (014340121)

Establishment				
Name	Address	ID/FEI	Business Operations	
Kelada Creative Group LLC DBA SALVE		0 14340 121	manufacture(71157-0017)	

Revised: 12/2016 Kelada Creative Group LLC DBA SALVE