

**AK47 MENTHOL COOLING CREAM PACKET- menthol cream
RENU LABORATORIES, 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.

AK4 7 MENTHOL COOLING CREAM PACKET

Active Ingredient

Menthol 5 %

Purpose

Topical Analgesic

Uses

for temporary relief of minor aches and pains of muscles and joints associated with

- bruises
- sprains
- arthritis
- strains

When using this product

Do not bandage tightly

- avoid contact with eyes
- do not apply to wounds or damaged skin
- do not use with heating pads or other heating devices

Stop use and ask a doctor if

- Condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years of age and older, apply to affected area no more than 10 times a day as needed for pain.
- children under 12 years of age, do not use, consult a doctor.

Butyrospermum Parkii (Shea Butter), Cannabis Sativa (Hemp) Seed Oil and Hemp Derived Cannabidiol (CBD) with proprietary terpene blend (Limonene, Myrcene, Caryophyllene, Linalool, Pinene, Terpeneol), Cetearyl Alcohol, Cetearyl Glucoside, Cocos Nucifera (Coconut) Oil, C13-14 Isoparaffin, Deionized Water, Emulsifying Wax, Fragrance, Glyceryl Stearate, Hamamelis Virginiana (Witch Hazel), Laureth-7, Magnesium Chloride, Mangifera Indica (Mango) Seed Butter, Mentha piperita (Peppermint) Leaf Oil, Olea Europaea (Olive) Fruit Oil, Olus Oil (vegetable), PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Stearic Acid.

info@ak47painrelief.com

For external use only.

AND PRODUCT BOX

BOX OF 10

AK47 MENTHOL COOLING CREAM PACKET

menthol cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-576	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.2 g in 4 g		
Inactive Ingredients				
Ingredient Name	Strength			
MYRCENE (UNII: 3M39CZS25B)				
LINALOOL, (+)- (UNII: F4VNO44C09)				
WHITE WAX (UNII: 7G1J5DA97F)				
COCONUT OIL (UNII: Q9L0073W7L)				
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)				
OLIVE OIL (UNII: 6UYK2W1W1E)				
PEG-100 STEARATE (UNII: YD01N1999R)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
WATER (UNII: 059QF0K00R)				
CANNABIDIOL (UNII: 19GBJ60SN5)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
WITCH HAZEL (UNII: 101I4J0U34)				
SHEA BUTTER (UNII: K49155WL9Y)				
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)				
LIMONENE, (+)- (UNII: GFD7C86Q1W)				
CARYOPHYLLENE (UNII: BHW853AU9H)				
PINENE (UNII: 996299PUKB)				
TERPINEOL (UNII: R53Q4ZWC99)				
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)				
CORN OIL (UNII: 8470G57WFM)				
MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-576-10	10 in 1 BOX	08/13/2020	
1	NDC:76348-576-04	4 g in 1 PACKET; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	08/13/2020		

Labeler - RENU LABORATORIES, INC. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

