KALAYA BACK AND NECK PAIN RELIEF- methyl salicylate, menthol, camphor liquid Avaria Health & Beauty Corp

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.

Drug Facts

Active ingredients

Camphor 11% Menthol 16% Methyl salicylate 25%

Purpose

Topical Analgesic

Uses

Provides penetrating pain relief for the temporary relief of minor aches and pains of muscles and joints

Warnings

For External Use Only. Flammable. Keep away from heat or flame.

Do not use:

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

When using this product avoid contact with eyes or mucous membranes, do not bandage tightly.

Stop use and ask a doctor if condition worsen or symptoms persist more than 7 days, symptoms clear up and occur again within a few days and/or excessive skin irritation occurs.

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 and over: Spray evenly onto affected areas no more than 3 to 4 times daily. Apply spray to affected areas and

allowed to dry or thoroughly massage until penetrated. Wash hands with soap and water after use.

Other information

• Store at 59°F - 77°F

Inactive ingredients

Alcohol Denat., Cannabis Sativa Seed Oil, Citric Acid, Mentha Piperita (Peppermint) Oil

Questions or comments?

Call toll-free 1.888.829.7165

Product label



KALAYA BACK AND NECK PAIN RELIEF

methyl salicylate, menthol, camphor liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43493-0009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ)	METHYL SALICYLATE	25 g in 100 mL	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	16 g in 100 mL	

CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) -	CAMPHOD (NATURAL)	11 g
UNII:N20HL7Q941)	CAMPHOR (NATURAL)	in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)		
EUCALYPTUS OIL (UNII: 2R04ONI662)		
PEPPERMINT OIL (UNII: AV092KU4JH)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:43493- 0009-0	1 in 1 BOX	02/16/2023	
1	60 mL in 1 BOTTLE, SPRAY; 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	02/16/2023	

Labeler - Avaria Health & Beauty Corp (251366043)

Revised: 2/2023 Avaria Health & Beauty Corp