

**KALAYA PAIN RELIEF 6X WITH ARNICA - PAIN RELIEF- methyl salicylate,
menthol, camphor cream
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 4%,

Menthol 4%,

Methyl salicylate 11%

Purpose

Topical Analgesic

Uses

Penetrating pain relief for the temporary relief of minor aches and pains of muscle and joint pain associated with arthritis, backache, strains, sprains and bruises.

Warnings

• **For external use only**

Do not use

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

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly
- **do not point towards face while squeezing**

Stop use and ask a doctor

- condition worsen or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- 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. Use no more than 3-4 times daily. Apply cream to affected areas and thoroughly massage until penetrated. Wash hands with soap and water after use.

Other information

- Store at 59°F - 77°F

Inactive ingredients

water, rice bran oil, cetyl alcohol, isopropyl palmitate, sodium hydroxide, glycerin, eucalyptus oil, arnica montana, carbomer copolymer type a, ceteth-10 phosphate, dihexadecyl phosphate, dimethyl sulfone, dimethyl sulfone, diethylene glycol monophenyl ether

Questions or comments?

Call toll-free 1.888.829.7165

Product label

NDC 43493-0008-1



Kalaya

PAIN RELIEF

6x ACTIVE RELIEF

CREAM

with Arnica

Net Wt. 1.75 oz (50g)

Drug Facts

Active ingredients	Purpose
Camphor 4%	Topical Analgesic
Menthol 4%	Topical Analgesic
Methyl Salicylate 11%	Topical Analgesic

Uses - Provides penetrating pain relief for the temporary relief of minor aches and pains of muscles and joints associated with arthritis, backache, strains, sprains and bruises.

Warnings - For external use only. 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 worsens or symptoms persist for more than 7 days - symptoms clear up and occur again within a few days - 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 of age and older: Apply to affected area no more than 3 to 4 times daily. Children under 12 years of age: consult a physician. Apply cream to affected areas and thoroughly massage until penetrated. Wash hands with soap and water after use.

Other information - Store at 59°F - 77°F. If seal is broken, do not use

Inactive ingredients: Arnica Montana Flower Extract, Carbomer, Cetearyl Alcohol, Cetyl-10 Phosphate, Dicapryl Phosphate, Ethylhexyl Stearate, Eucalyptus Globulus Leaf Oil, Glycerin, Hemp Seed Oil, Isopropyl Palmate, Methylsulfonylethane (MSM), Oryza Sativa (Rice) Bran Oil, Phenylethanol, Sodium Hydroxide, Water

Questions or comments? Call toll-free 1.888.823.7165

Manufactured for: Avaria Health & Beauty Corp. Unit 5, 650 Jamieson Pky, Cambridge, ON N3C 0A5, CAN. MADE IN CANADA. www.kalayahealth.com 6 91808 09432 4



NDC 43493-0008-0



kalaya.

**PAIN
RELIEF**

6x
ACTIVE RELIEF
CREAM
with Arnica

Net Wt. **4.2 oz (119g)**

Drug Facts

Active ingredients	Purpose
Camphor 4%	Topical Analgesic
Menthol 4%	Topical Analgesic
Methyl Salicylate 11%	Topical Analgesic

Uses ■ Provides penetrating pain relief for the temporary relief of minor aches and pains of muscles and joints associated with arthritis, backache, strains, sprains and bruises.

Warnings

■ For external use only.

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 worsens or symptoms persist for more than 7 days
■ symptoms clear up and occur again within a few days
■ 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 of age and older: Apply to affected area no more than 3 to 4 times daily. Children under 12 years of age: consult a physician.
■ Apply cream to affected areas and thoroughly massage until penetrated. ■ Wash hands with soap and water after use.

Other information

■ Store at 59°F - 77°F ■ If seal is broken, do not use

Inactive ingredients

Arnica Montana Flower Extract, Carbomer, Cetearyl Alcohol, Ceteth-10 Phosphate, Dicapryl Phosphate, Ethylhexylglycerin, Eucalyptus Globulus Leaf Oil, Glycerin, Hemp Seed Oil, Isopropyl Palmitate, Methylsulfonmethane (MSM), Oryza Sativa (Rice) Bran Oil, Phenoxethanol, Sodium Hydroxide, Water

Questions or comments?

Call toll-free 1.888.829.7165

Manufactured for:

Avaria Health & Beauty Corp.

Unit 5, 650 Jamieson Pky, Cambridge, ON N3C 0A5, CAN
MADE IN CANADA | www.kalayahealth.com



6 91808 09430 0

NDC 43493-0008-2



Kalaya[™]

PAIN RELIEF

6x

ACTIVE RELIEF

MASSAGE APPLICATOR

with Arnica

Net Wt. **4.2 oz** (119g)

Drug Facts

Active ingredients

Active ingredients	Purpose
Camphor 4%	Topical Analgesic
Menthol 4%	Topical Analgesic
Methyl Salicylate 11%	Topical Analgesic

Uses - Provides penetrating pain relief for the temporary relief of minor aches and pains of muscles and joints associated with arthritis, backache, strains, sprains and bruises.

Warnings

■ For external use only.

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 - do not point towards face while squeezing

Stop use and ask a doctor if - condition worsens or symptoms persist for more than 7 days - symptoms clear up and occur again within a few days - 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 of age and older:

Apply to affected area no more than 3 to 4 times daily.

Children under 12 years of age: consult a physician.

■ Apply cream to affected areas and thoroughly massage until penetrated. ■ Wash hands with soap and water after use.

Other information - Store at 59°F - 77°F

Inactive ingredients

Arnica Montana Flower Extract, Carbomer, Cetearyl Alcohol, Ceteth-10 Phosphate, Dicapryl Phosphate, Ethylhexylglycerin, Eucalyptus Globulus Leaf Oil, Glycerin, Hemp Seed Oil, Isopropyl Palmitate, Methylsulfonylmethane (MSM), Oryza Sativa (Rice) Bran Oil, Phenoxyethanol, Sodium Hydroxide, Water

Questions or comments? Call toll-free 1.888.829.7165

Manufactured for:

Avaria Health & Beauty Corp.

Unit 5, 650 Jamieson Pky, Cambridge, ON N3C 0A5, CAN

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KALAYA PAIN RELIEF 6X WITH ARNICA - PAIN RELIEF

methyl salicylate, menthol, camphor cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43493-0008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	11 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4 g in 100 g
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
RICE BRAN OIL (UNII: LZO6K1506A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCERIN (UNII: PDC6A3C0OX)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
ARNICA MONTANA (UNII: O80TY208ZW)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
DIETHYLENE GLYCOL MONOPHENYL ETHER (UNII: LZU6ET206Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43493-0008-0	1 in 1 BOX	01/30/2023	
1		119 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:43493-0008-1	1 in 1 BOX	01/30/2023	
2		50 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:43493-0008-2	1 in 1 BOX	01/30/2023	
3		119 g in 1 APPLICATOR; 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	04/07/2021	

Revised: 3/2023

Avaria Health & Beauty Corp