

KALAYA FOAMING 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 3%
Menthol 8%
Methyl salicylate 10%

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., Arnica Montana Flower Extract, Bis-Peg 12 Dimethicone, Bis-Peg 10 Dimethicone, Water

Questions or comments?

Call toll-free 1.888.829.7165

Product label



KALAYA FOAMING PAIN RELIEF

methyl salicylate, menthol, camphor liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:43493-0011 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | METHYL SALICYLATE | 10 g in 100 mL |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 8 g in 100 mL |

| | | |
|---|-------------------|---------------|
| CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941) | CAMPHOR (NATURAL) | 3 g in 100 mL |
|---|-------------------|---------------|

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ALCOHOL (UNII: 3K9958V90M) | |
| ARNICA MONTANA WHOLE (UNII: O80TY208ZW) | |
| BIS-PEG-12 DIMETHICONE (70 MPA.S) (UNII: 2JDK5W22H4) | |
| BIS-PEG-10 DIMETHICONE/DIMER DILINOLEATE COPOLYMER (UNII: CF5W1YCX11) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:43493-0011-0 | 1 in 1 BOX | 02/10/2023 | |
| 1 | | 80 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 | 02/10/2023 | |

Labeler - Avaria Health & Beauty Corp (251366043)

Revised: 2/2023

Avaria Health & Beauty Corp