

THAI HERBAL BALM LAVENDER - menthol and camphor (synthetic) ointment

Thai Herb and Spa

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.

Thai Herbal Balm Lavender

Ingredients

| Active Ingredients | Purpose |
|---------------------------|-------------------|
| Menthol 10% | Topical analgesic |
| Methyl Salicylate | Topical analgesic |

Use(s)

For sore muscles and over-exertion.

Provides soothing relief for aches and pains due to:

- Backaches
- Arthritis
- Joint Pains
- Stiffness
- Sprains
- Over-exertion

Directions

- Adults and children 12 years of age and older : Apply Thai Herbal Balm Lavender to affected area. Rub well on the affected area. Repeat 3 to 4 times daily.
- Children under 12 years of age: ask a doctor before use.

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.

Ask a doctor before

use if you have redness over the affected area.

When using this product

- Avoid contact with the 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 to avoid accidental ingestion.

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

Other Information

- This product may cause an allergic reaction in some individuals. Test on a small area before use.

Inactive Ingredients

Peppermint Oil, Camphor And Paraffin Petrolatum.

PRINCIPAL DISPLAY PANEL - 50g Jar

THAI HERBAL BALM

LAVENDER

PAIN RELIEVING OINTMENT

NET WT. 1.75 oz. (50g)



THAI HERBAL BALM LAVENDER

menthol and camphor (synthetic) ointment

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:75978-3049 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|---------------|
| Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A) | Menthol | 2.5 g in 50 g |
| Camphor (synthetic) (UNII: 5TJD82A1ET) (Camphor (synthetic) - UNII:5TJD82A1ET) | Camphor (synthetic) | 1.5 g in 50 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------------|----------------|
| Lavender Oil (UNII: ZBP1YXW0H8) | 2.5 g in 50 g |
| Peppermint Oil (UNII: AV092KU4JH) | 2.5 g in 50 g |
| Methyl Salicylate (UNII: LAV5U5022Y) | 6 g in 50 g |
| Paraffin (UNII: I9O0E3H2ZE) | 7.5 g in 50 g |
| Petrolatum (UNII: 4T6H12BN9U) | 27.5 g in 50 g |

Product Characteristics

| | | | |
|----------|---------------------|--------------|--|
| Color | white (white cream) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:75978-3049-1 | 1 in 1 BOX | | |
| 1 | | 50 g in 1 JAR | | |
| 2 | NDC:75978-3049-2 | 1 in 1 BOX | | |
| 2 | | 20 g in 1 JAR | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 01/09/2007 | |

Labeler - Thai Herb and Spa (195629303)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|---------------------|
| THANYAPORN HERBS CO.,LTD. | | 660966151 | manufacture |

Revised: 3/2012

Thai Herb and Spa