

MATA BALM - camphor, menthol ointment

Amata LLC

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 Ingredient

Camphor 4.5%

Menthol 37%

Purpose

Topical Analgesic

Keep out of reach of children

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

Uses

For temporarily relief of pain and itching associated with insect bites, minor skin irritations and infections,

rashes, boils, minor aches and pains of muscles and joints, dizziness

Warnings

For external use only

When using this product

- Use only as directed
- Do not apply to wounds and broken skin
- Avoid contact with eyes

Stop use and ask a doctor if

- condition worsens
- severe skin irritation occurs
- symptoms persist for more than 7 days or clear up and reoccur within a few days

Directions

Apply thin layer to or rub gently upon the desired area or inhale as needed. Repeat 3 to 4 times daily. For infants under 12 months of age, consult physician before use

Inactive Ingredients

Aloe Vera, Barleria Lupulina, Beach Morning Glory, Betel leaf, Clinacanthus Nutans Lindau, Coconut oil, Crinum Veld Lily, Garden Quinine, Paraffin, Petrolatum, Zingiber Cassamunar.

Other Information:

This product may cause allergic reaction in some individuals, test on small area before use

Store at 68° to 85°F (20° to 30°C)



Drug Facts (continued)

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Questions/Comments (347) 541-MATA (6282)
Manufactured for Amata LLC, New York, NY 10016
www.mata-samui.com **Made in Thailand**

100% virgin coconut oil based 100% alcohol free
100% all natural 100% cruelty free

All natural herbal balm, virgin coconut oil based and made from 8 different herbs, each of which has its own healing qualities. Hand-picked straight from our organic family farm on the lush, tropical island of Koh Samui, Thailand. Give it a try, we're convinced you'll love it!

Mata's mission is to deliver only the highest-quality, all-natural herbal products, from our Herbal Healing Balm and Inhaler, to our Insect Repellent and assorted Aloe Vera Gels. Founded in 2005 by Mrs. Sopa Mata, certified Thai traditional herbalist and owner of SriRama Herbal Garden where all our fresh ingredients come from.

NDC 58167-112-30

mata balm™

ALL-PURPOSE HERBAL HEALING OINTMENT

Soothes itches, insect bites, muscle aches and pains

Net Wt 1 oz (30g) **TOPICAL ANALGESIC**

LOT 5603001
EXP 03/2016

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|--------------------|-------------------|
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MATA BALM

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Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58 167-112 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941) | CAMPHOR (NATURAL) | 45 mg in 1 g |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 367 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| BARLERIA PRIONITIS WHOLE (UNII: 8GSN1J79JM) | |
| IPOMOEA PES-CAPRAE FLOWERING TOP (UNII: 0SJ345C829) | |
| PIPER BETLE LEAF (UNII: NT24A1359E) | |
| CAJANUS CAJAN LEAF (UNII: DP2IW63584) | |
| COCONUT OIL (UNII: Q9L0O73W7L) | |
| QUININE (UNII: A7V27PHC7A) | |
| PARAFFIN (UNII: I9O0E3H2ZE) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| ZINGIBER MONTANUM FLOWERING TOP (UNII: P614KWN5QY) | |
| CRINUM ASIATICUM WHOLE (UNII: 4A0W54S52I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:58167-112-30 | 1 in 1 BOX | | |
| 1 | | 30 g in 1 JAR | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 04/27/2013 | |

Labeler - Amata LLC (078743307)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------|---------|-----------|------------------------|
| Sopa Suthayalai | | 661732799 | manufacture(58167-112) |

Revised: 5/2013

Amata LLC