

## **WOMENS SPORTS BALM- camphor, eucalyptus oil, menthol, methyl salicylate cream**

**Dr.Sankunni's Ayurvedic Research Foundation Private Limited**

*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.*

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### **Womens Sports Balm**

#### **Active Ingredients Purpose**

|   |                   |
|---|-------------------|
| Camphor 11%                             | Topical Analgesic |
| Eucalyptus Oil 10%                      | Anti-Inflammatory |
| Menthol 8%                              | Topical Analgesic |
| Wintergreen Oil (Methyl Salicylate) 10% | Topical Analgesic |

**Uses**: Temporarily relieves minor aches & pains related to

- arthritis
- Menstrual cramps
- backaches
- bursitis
- sore muscles
- joint pain
- leg cramps
- bruises
- sprains
- sports and other minor injuries

#### **Keep out of reach of children to avoid accidental ingestion.**

If swallowed, get medical help or contact a poison control center immediately.

ZEN

for aches & pains

all natural relief balm coconut oil

ideal for:

aches & pains related to

rheumatoid arthritis

joint pain

backaches

bursitis

sore muscles

arthritis

leg cramps

sprains and strains

☐ **Directions:**

- use only as directed
- apply generously to affected area 3 to 4 times daily
- children under 12, consult a doctor before use.

☐ **WARNINGS For external use only**

**When using this product**

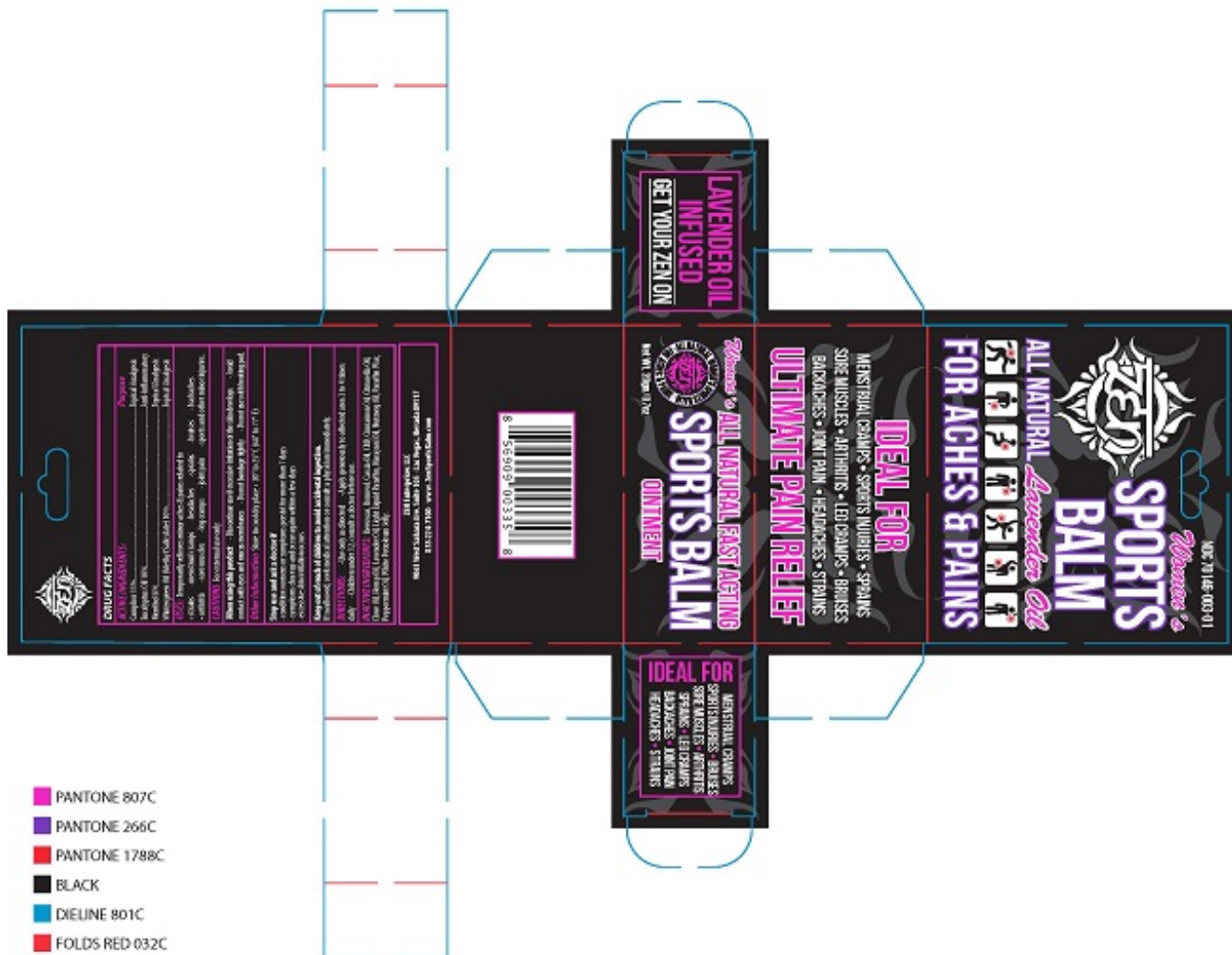
- discontinue use if excessive irritation of the skin develops
- avoid contact with eyes and mucus membranes
- do not bandage tightly
- do not use with heating pad

**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

☐ **Inactive Ingredients**

coconut oil, paraffin wax, white petroleum jelly, light liquid paraffin, beeswax, clove oil, nutmeg oil, cassia oil, cinnamon oil, peppermint oil, borneol, citronella oil



## WOMENS SPORTS BALM

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### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:70146-011 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength         |
|---|-------------------|------------------|
| <b>CAMPHOR (NATURAL)</b> (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941) | CAMPHOR (NATURAL) | 11 g<br>in 100 g |
| <b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)       | EUCALYPTUS OIL    | 10 g<br>in 100 g |
| <b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)                     | MENTHOL           | 8 g in 100 g     |
| <b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)    | METHYL SALICYLATE | 10 g<br>in 100 g |

### Inactive Ingredients

| Ingredient Name                                | Strength |
|--|----------|
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)          |          |
| <b>PARAFFIN</b> (UNII: I9O0E3H2ZE)             |          |
| <b>PETROLATUM</b> (UNII: 4T6H12BN9U)           |          |
| <b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)    |          |
| <b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)           |          |
| <b>CLOVE OIL</b> (UNII: 578389D6D0)            |          |
| <b>NUTMEG OIL</b> (UNII: Z1CLM48948)           |          |
| <b>CHINESE CINNAMON OIL</b> (UNII: A4WO0626T5) |          |
| <b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)       |          |
| <b>BORNEOL</b> (UNII: M89NIB437X)              |          |
| <b>CITRONELLA OIL</b> (UNII: QYO8Q067D0)       |          |
| <b>CINNAMON OIL</b> (UNII: E5GY4I6YCZ)         |          |
| <b>HEMP</b> (UNII: TD1MUT01Q7)                 |          |
| <b>PADANG CASSIA OIL</b> (UNII: 0E15252LIW)    |          |
| <b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)         |          |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70146-011-00 | 20 g in 1 JAR; Type 0: Not a Combination Product | 10/25/2016           |                    |

### Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348                                  | 10/25/2016           |                    |

**Labeler** - Dr.Sankunni's Ayurvedic Research Foundation Private Limited (650517704)

### Establishment

| Name  | Address | ID/FEI    | Business Operations    |
|---|---------|-----------|------------------------|
| Dr.Sankunni's Ayurvedic Research Foundation Private Limited |         | 650517704 | manufacture(70146-011) |

Revised: 6/2021

Dr.Sankunni's Ayurvedic Research Foundation Private Limited