

WOMENS RELIEF 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.

Womens Relief 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
- headaches
- bursitis
- sore muscles
- joint pain
- leg cramps
- bruises
- sprains
- strains

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

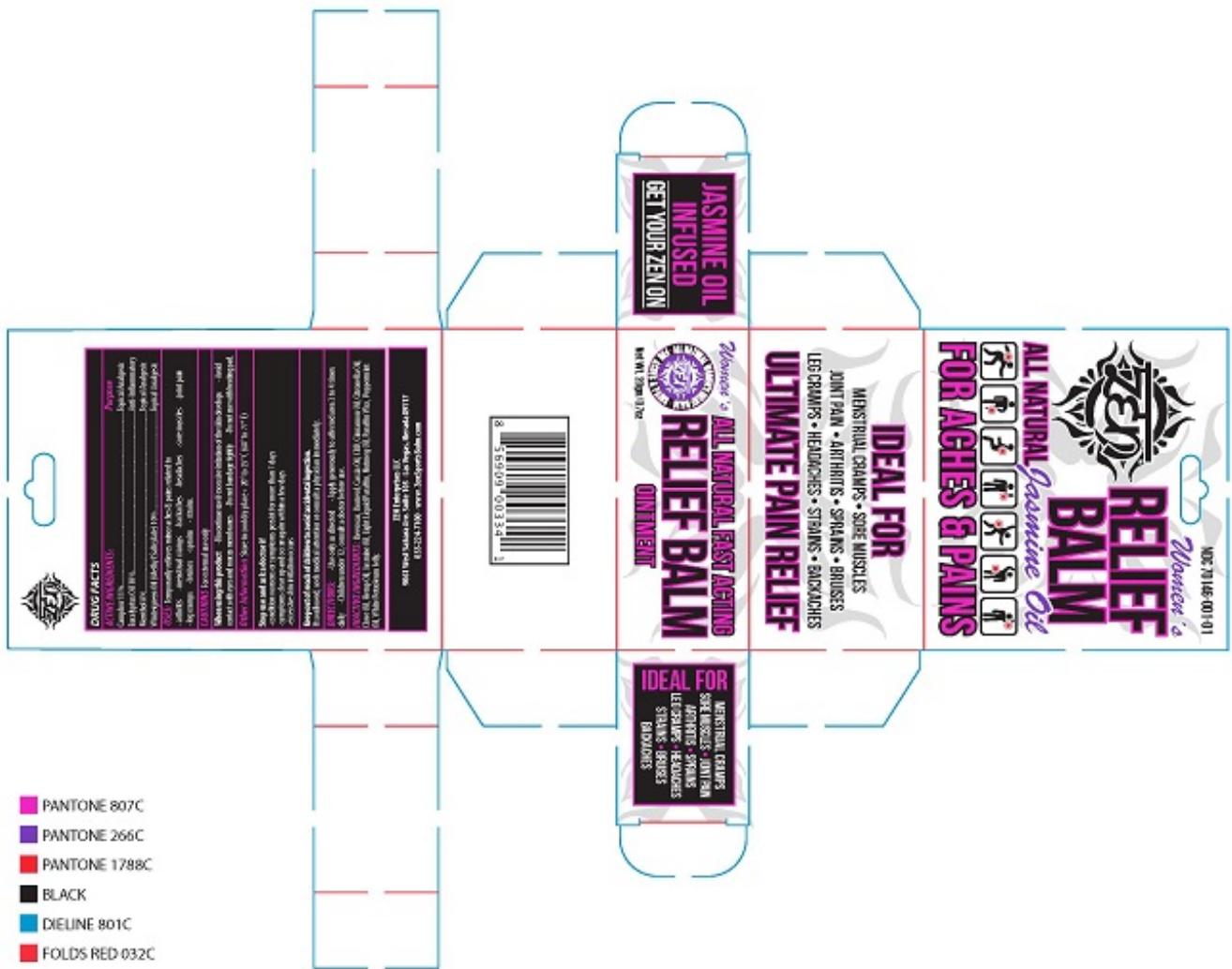
- discontinue use if excessive irritation of the skin develops
- avoid contact with eyes and mucus membranes
- do not bandage tightly
- do not use with heating pad

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, Jasmine oil



WOMENS RELIEF BALM

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70146-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
JASMINE LACTONE (UNII: H8558L43SR)	
COCONUT OIL (UNII: Q9L0O73W7L)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CLOVE OIL (UNII: 578389D6D0)	
NUTMEG OIL (UNII: Z1CLM48948)	
CHINESE CINNAMON OIL (UNII: A4WO0626T5)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
BORNEOL (UNII: M89NIB437X)	
CITRONELLA OIL (UNII: QYO8Q067D0)	
CINNAMON OIL (UNII: E5GY4I6Y CZ)	
HEMP (UNII: TD1MUT01Q7)	
PADANG CASSIA OIL (UNII: 0E15252LIW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70146-010-00	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(70146-010)

Revised: 6/2021

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