

WOMENS SPORTS BALM- camphor, eucalyptus oil, menthol 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 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 in muscles and joints related to

- strains
- menstrual cramps
- mild migraines
- sprains
- bruises
- backaches
- arthritis
- 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.

☐**Inactive Ingredients**

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

ZEN

for aches & pains

women's sports balm lavender oil

ideal for:

aches & pains related to

sports injuries

minor arthritis

sore muscles

leg cramps

cramps

strains and sprains

Directions:

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

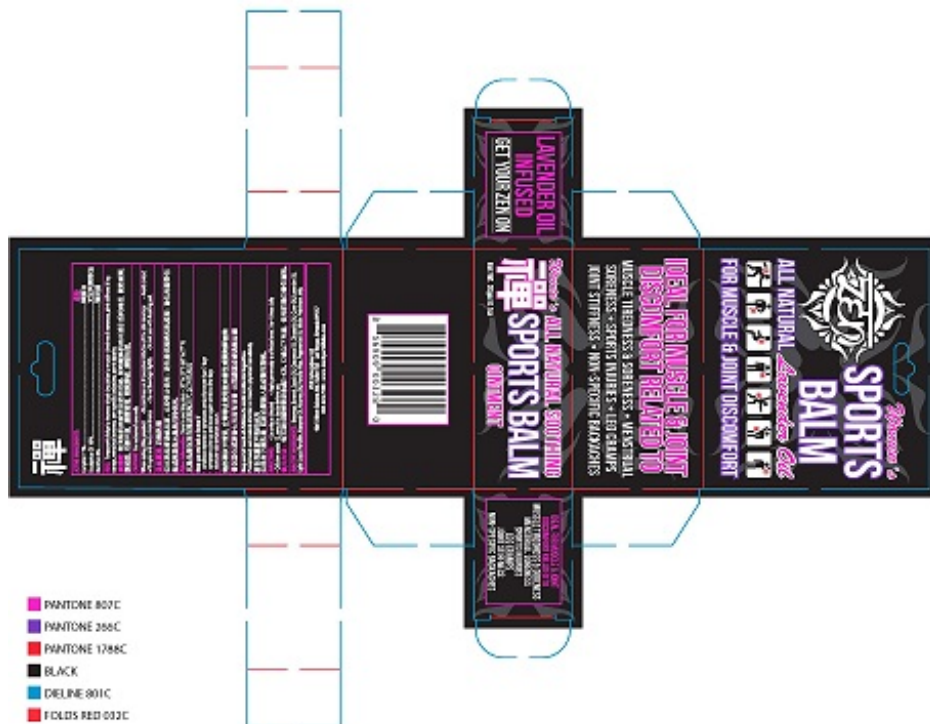
WARNINGS For external use only

When using this product

- discontinue use if excessive irritation of the skin develops
- avoid contact with eyes and mucous 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



WOMENS SPORTS BALM

camphor, eucalyptus oil, menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70146-007
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

Inactive Ingredients

Ingredient Name	Strength
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)	
CINNAMON OIL (UNII: E5GY4I6YCZ)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
BORNEOL (UNII: M89NIB437X)	
CITRONELLA OIL (UNII: QYO8Q067D0)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70146-007-01	5 g in 1 JAR; Type 0: Not a Combination Product	07/21/2016	
2	NDC:70146-007-02	20 g in 1 JAR; Type 0: Not a Combination Product	07/21/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/21/2016	

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(70146-007)