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.

□ **Uses**□: Temporarily relieves minor aches & pains in muscles and joints related to

- strains
- 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.

ZEN

for aches & pains

all natural sports balm

ideal for:

aches & pains related to

sports injuries

minor arthritis

sore muscles

leg 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 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

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

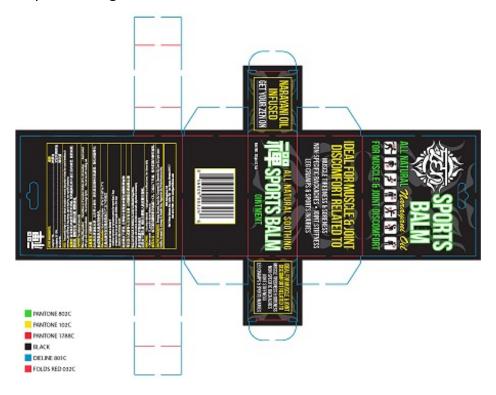
Active Ingredients Purpose

Camphor 11% Topical Analgesic

Eucalyptus Oil 10% Anti-Inflammatory

Menthol 8% Topical Analgesic

Topical Analgesic



SPORTS BALM

camphor, eucalyptus oil, menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70146-005

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: 2R040NI662) (EUCALYPTUS OIL - UNII:2R040NI662)	EUCALYPTUS OIL	10 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
PARAFFIN (UNII: 1900E3H2ZE)			
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)			

Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70146-005- 01	5 g in 1 JAR; Type 0: Not a Combination Product	07/21/2016	
2	NDC:70146-005- 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		
illiai				

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(70146-005)	

Revised: 6/2021 Dr.Sankunni's Ayurvedic Research Foundation Private Limited