## 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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#### **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
- 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

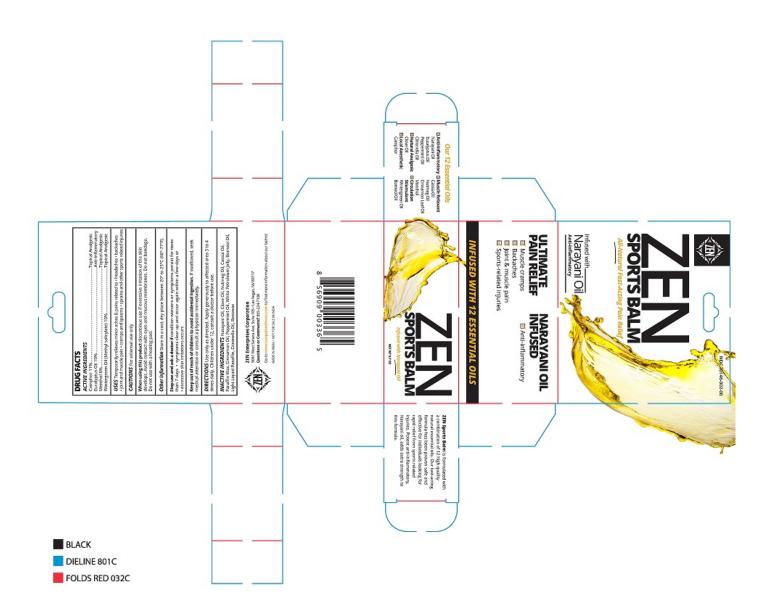
#### Stop use and ask a doctor if

- 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





#### **SPORTS BALM**

camphor, eucalyptus oil, menthol, methyl salicylate cream

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:70146-002 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		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ)	METHYL SALICYLATE	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)			
<b>CLOVE OIL</b> (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)			

F	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:70146-002-	5 g in 1 JAR; Type 0: Not a Combination Product	10/19/2015	01/19/2016	
2	NDC:70146-002- 01	5 g in 1 JAR; Type 0: Not a Combination Product	01/18/2016		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	10/15/2015		

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

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Dr.Sankunni's Ayurvedic Research Foundation Private Limited		650517704	manufacture(70146-002)	

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