

RELIEF 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 related to

- arthritis
- backaches
- bursitis
- sore muscles
- joint pain
- leg cramps
- bruises
- sprains

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

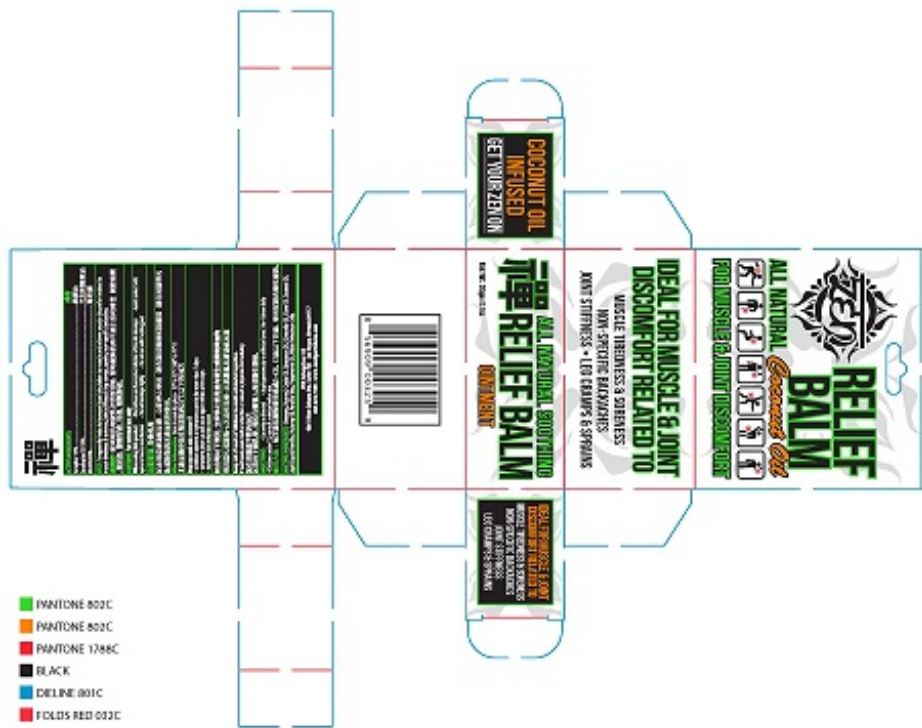
coconut oil, paraffin wax, white petroleum jelly, light liquid paraffin, beeswax, clove oil, nutmeg oil, cassia oil, cinnamon oil, peppermint oil, borneol, citronella oil

Active Ingredients Purpose

Camphor 11% Topical Analgesic

Eucalyptus Oil 10% Anti-Inflammatory

Menthol 8% Topical Analgesic



RELIEF BALM

camphor, eucalyptus oil, menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70146-004
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
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70146-004-01	5 g in 1 JAR; Type 0: Not a Combination Product	07/21/2016	
2	NDC:70146-004-02	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(70146-004)