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.

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

MKeep 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.

UWARNINGS 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







2.6575"



3.1496"

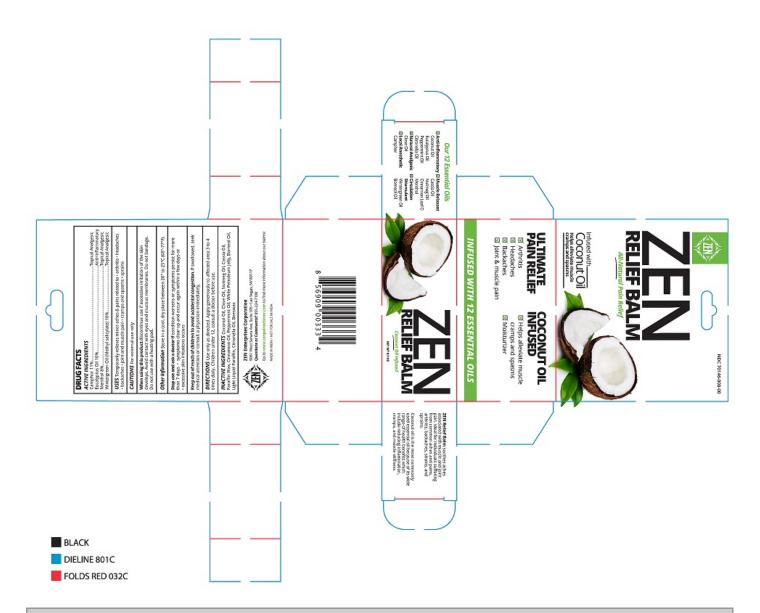
Full Color CMYK and 2 Spot Colors:

Pantone: 802 C

Pantone: 151 C



DIELINE



RELIEF BALM

camphor, eucalyptus oil, menthol, methyl salicylate cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70146-000	
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	10 g in 100 g		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength

COCONUT OIL (UNII: Q9L0O73W7L)	
PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E)	
PETROLATUM (UNII: 4T6H12BN9U)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CLOVE OIL (UNII: 578389 D6 D0)	
NUTMEG OIL (UNII: Z1CLM48948)	
CHINESE CINNAMON OIL (UNII: A4WO0626T5)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
BORNEOL (UNII: M89 NIB437X)	
CITRONELLA OIL (UNII: QYO8Q067D0)	

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:70146-000-00	20 g in 1 JAR; Type 0: Not a Combination Product	10/19/2015		
2	NDC:70146-000-01	5 g in 1 JAR; Type 0: Not a Combination Product	0 1/18/20 16		
3	NDC:70146-000-02	5 g in 1 JAR; Type 0: Not a Combination Product	0 1/18/20 16	01/19/2016	

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	Business Operations	
Dr.Sankunni's Ayurvedic Research Foundation Private Limited		650517704	manufacture(70146-000)	

Revised: 6/2019 Dr.Sankunni's Ayurvedic Research Foundation Private Limited