

ZEN HEMP BALM- camphor, eucalyptus oil, menthol, methyl salicylate cream

Zen Enterprises LLC

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.

Zen Hemp Balm

Active Ingredients.....Purpose

Camphor 11%.....Topical Analgesic

Eucalyptus Oil 10%.....Anti-Inflammatory

Menthol 8%.....Topical Analgesic

Wintergreen Oil (Methyl Salicylate) 10%....Topical Analgesic

Active Ingredients.....Purpose

Camphor 11%.....Topical Analgesic

Eucalyptus Oil 10%.....Anti-Inflammatory

Menthol 8%.....Topical Analgesic

Wintergreen Oil (Methyl Salicylate) 10%....Topical Analgesic

Keep out of reach of children to avoid accidental ingestion.

If swallowed, seek medical attention or consult a physician immediately.

Uses: Temporarily relieves minor aches & pains related to

- headaches
- backaches
- joint and muscle pain
- cramps and spasms
- sprains and other sports related injuries

☐Directions:

Use only as directed. Apply generously to affected area 3 to 4 times daily. Children under 12, consult a doctor before use.

☐Inactive Ingredients

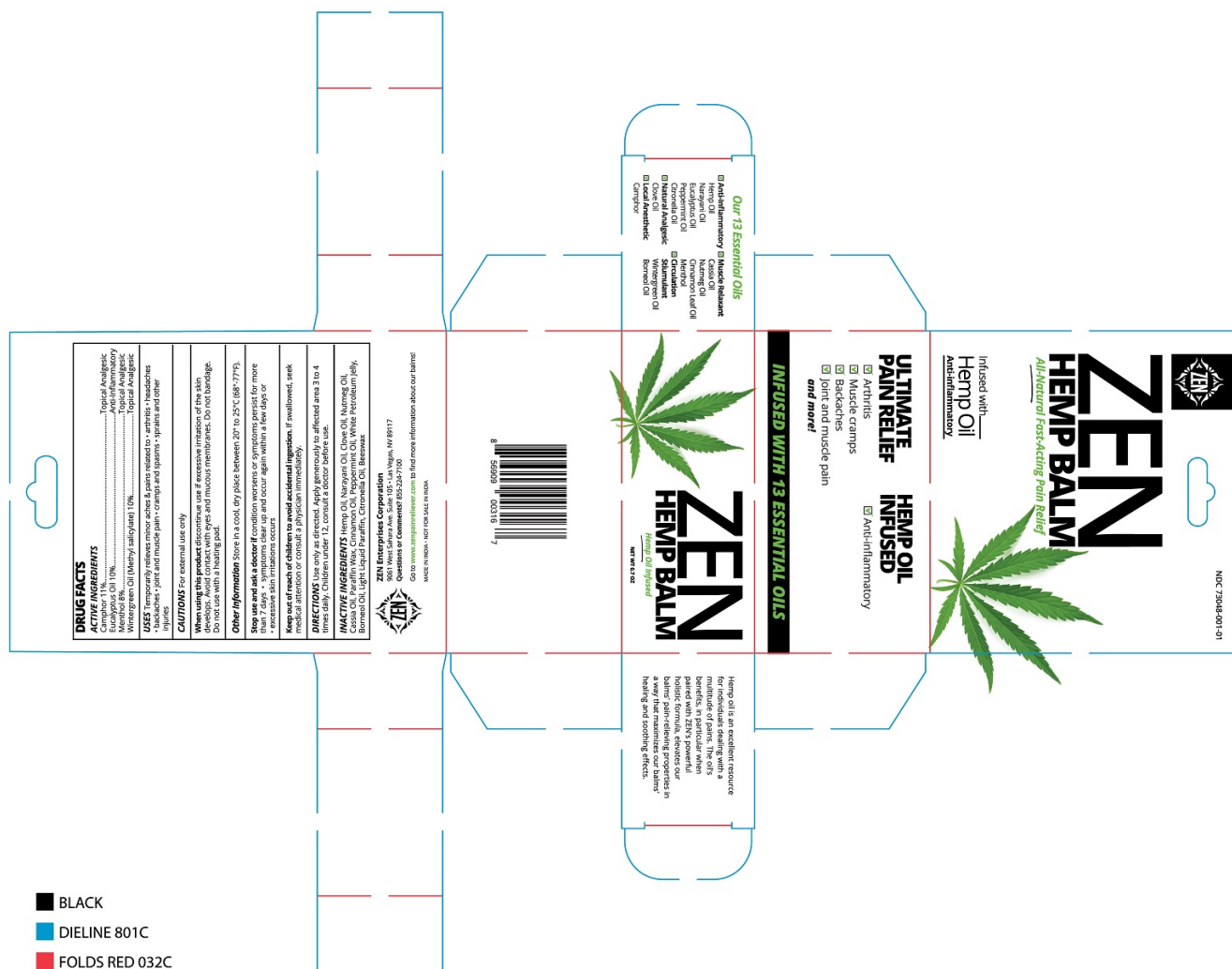
Narayani Oil, Clove Oil, Nutmeg Oil, Cassia Oil, Paraffin Wax, Cinnamon Oil, Peppermint Oil, White Petroleum Jelly, Borneol, Light Liquid Paraffin, Citronella Oil, Beeswax

CAUTIONS

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. Do not use with a 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 or
 - excessive skin irritation occurs



ZEN HEMP BALM			
camphor, eucalyptus oil, menthol, methyl salicylate cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73048-001
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
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
CLOVE OIL (UNII: 578389D6D0)	
NUTMEG OIL (UNII: Z1CLM48948)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
BORNEOL (UNII: M89NIB437X)	
CITRONELLA OIL (UNII: QYO8Q067D0)	
CINNAMON OIL (UNII: E5GY4I6YCZ)	
HEMP (UNII: TD1MUT01Q7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73048-001-01	20 g in 1 JAR; Type 0: Not a Combination Product	04/22/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/22/2019	

Labeler - Zen Enterprises LLC (063099830)

Establishment

Name	Address	ID/FEI	Business Operations
Dr.Sankunni's Ayurvedic Research Foundation Private Limited		650517704	manufacture(73048-001)

Revised: 6/2021

Zen Enterprises LLC