PAIN RELIEVING ROLL-ON GEL- menthol, 10% gel
Koi CBD 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.

Koi Muscle Gel Roll-On

Pain Relieving Roll-On Gel

Active ingredient Purpose

Menthol 10%.....Cooling Pain Reliever

Uses: For the temporary relief of minor aches and pains of muscles and joints associated with:

• backache • arthritis • strains • bruises • sprains

Warnings: For external use only

Flammable: Keep away from excessive heat or open flame.

When using this product: Avoid contact with the eyes. If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of product and consult a physician. Do not apply to wounds or damaged skin. Do not bandage tightly.

Do not use in eyes. In case of contact, rinse thoroughly with water.

Directions

Adults and children 2 years of age and older: Apply to the affected area not more than 3 to 4 times daily. **Children under 2 years of age:** consult a physician.

If pregnant or breastfeeding: Ask a health professional before use.

Keep out of reach of children: If accidentally ingested, get medical help or contact a Poison Control Center immediately.

Store in a cool dry place with lid closed tightly.

Inactive Ingredients: Organic Aloe Leaf Juice, Ethyl Alcohol, White Camphor Essential Oil, Meadowfoam Seed Oil, Cannabidiol (CBD)

from Hemp Extract, Capsicum Fruit Oleoresin, Sweet Basil Leaf Oil, Black Pepper Oil, Roman Chamomile Flower Oil, German Chamomile Flower Oil, Cinnamon Leaf Oil, Citronella Oil, Eucalyptus Leaf Oil, Helichrysum Flower Oil, Ginger Root Oil, Pink Grapefruit Peel Oil, Juniper Berry Oil, Lemongrass Oil, Peppermint Oil, Pine Needle Oil, Ravensara Oil, Rosemary Leaf Oil, Spearmint Oil, Wild Oregano Oil, Glycerin, Witch Hazel Water, Organic Alcohol, Phenoxyethanol, Carbomer, Triethanolamine, Tetrasodium Glutamate Diacetate

Questions or Comments? (877) 744-4779

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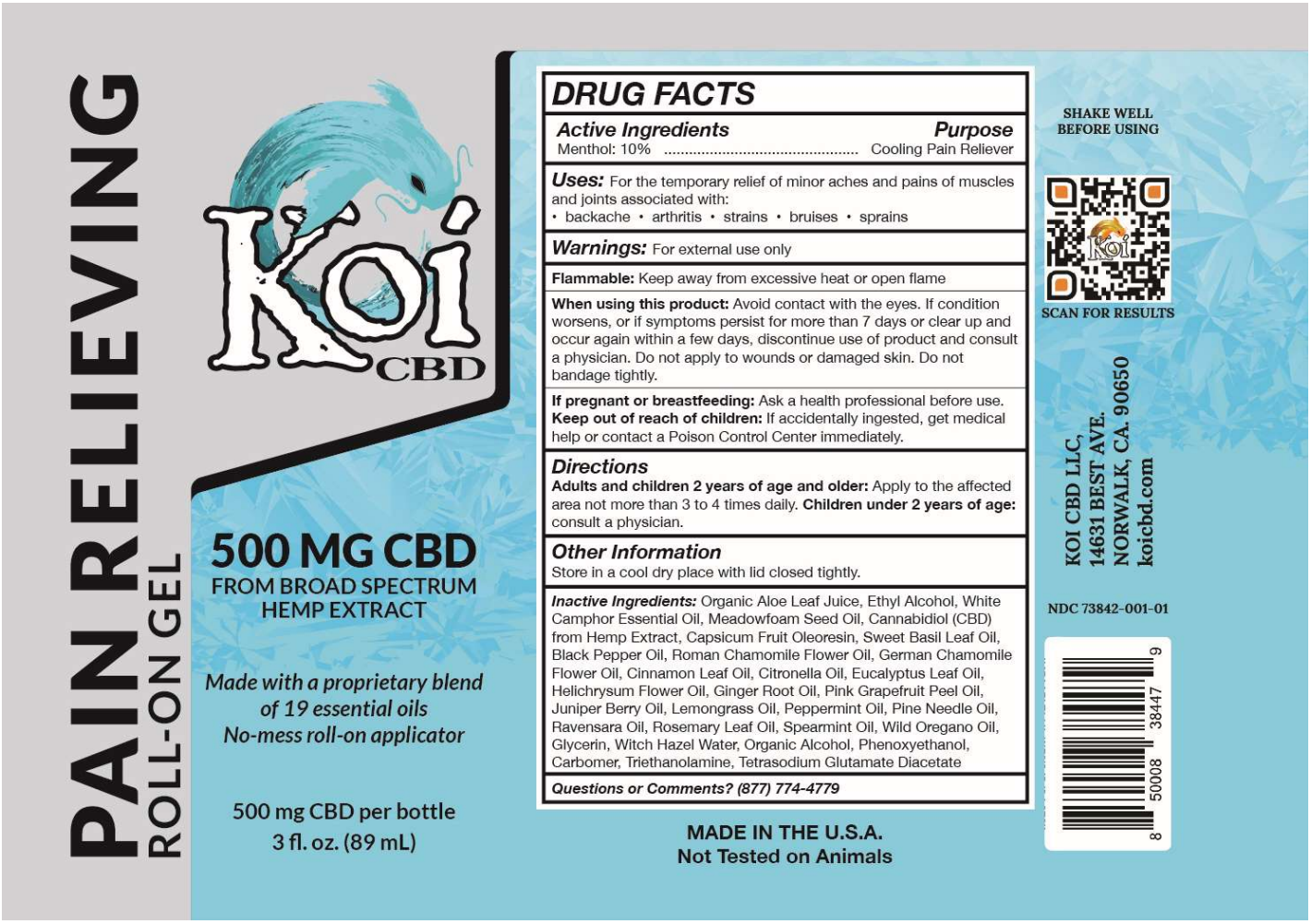
Individual Unit Label

NDC 73842-001-01 Roll On Bottle 89 mL



Pain Relieving Roll-On Gel 6-pack Label

NDC 73842-001-02 Case of 6 bottles (Net Vol. 534 mL)

PAIN RELIEVING ROLL-ON GEL

menthol, 10% gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73842-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CINNAMON LEAF OIL (UNII: S92U8SQ71V)	
CITRONELLA OIL (UNII: QYO8Q067D0)	
GRAPEFRUIT OIL (UNII: YR377U58W9)	
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	
ALOE ARBORESCENS LEAF (UNII: 09TD8L5SQV)	
CAMPHOR OIL, WHITE (UNII: 26P3H26Z9X)	

MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
CAPSICUM OLEORESIN (UNII: UW86K581WY)	
BLACK PEPPER OIL (UNII: U17J84S19Z)	
BASIL (UNII: 2U0KZP0FDW)	
TROLAMINE (UNII: 9O3K93S3TK)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
HELICHRYSUM ITALICUM FLOWER OIL (UNII: O97ZV7726K)	
GINGER OIL (UNII: SAS9Z1SVUK)	
JUNIPER BERRY OIL (UNII: SZH16H44UY)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
PINE NEEDLE OIL (PINUS SYLVESTRIS) (UNII: 5EXL5H740Y)	
CRYPTOCARYA AGATHOPHYLLA LEAF OIL (UNII: XM00Z00H98)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
SPEARMINT OIL (UNII: C3M81465G5)	
OREGANO LEAF OIL (UNII: 7D0CGR40U1)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CANNABIS SATIVA FLOWERING TOP (UNII: 8X454SZ22D)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WITCH HAZEL (UNII: 101I4J0U34)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color	orange (Light orange)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73842-001-01	89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	05/25/2020	
2	NDC:73842-001-02	534 mL in 1 CASE; Type 0: Not a Combination Product	05/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/20/2020	

Labeler - Koi CBD LLC (072518336)

Registrant - Brad Ridenour (072518336)

Establishment

Name	Address	ID/FEI	Business Operations
Koi CBD LLC		072518336	manufacture(73842-001)