

REINA CBD INFUSED TOPICAL PAIN RELIEF- methyl salicylate, menthol lotion
Reina Wellness 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.

REINA CBD INFUSED TOPICAL PAIN RELIEF LOTION

DRUG FACTS

ACTIVE INGREDIENTS:

Methyl Salicylate 10%

Menthol 4%

PURPOSE

Topical Analgesic

USES:

Temporarily relieves inflammation, mild aches and pains of muscle joints.

WARNINGS:

Only for external use.

Do not use:

on open wounds, cuts damaged or infected skin as well as in the eyes, mouth, genitals, or any other mucous membranes.

Consult your physician:

- if pain is persistent or worsens or if using any other topical pain products.
- Call poison control if swallowed. If contact with eyes occurs, rinse eyes thoroughly with cold water.

Keep out of reach of children.

Consult physician for children under 12.

DIRECTIONS: (Store in a cool dry place)

Wash and dry affected area. Shake bottle well before each use and gently rub over area of pain. Use is not recommended more than four times a day. Wash hands immediately afterwards and avoid contact with eyes.

INACTIVE INGREDIENTS:

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, C12-15 Alkyl Benzoate, Cannabis Sativus (Full Spectrum Hemp) Seed Oil, Capsaicin, Chamomilla Recutita (Chamomile) Extract, Cetearyl Oliviate, Cetyl Alcohol, Cetyl Myristoleate, Chondroitin Sulfate, Gluconolactone, Glucosamine Sulfate, Glycerin, Glyceryl Stearate,

Glycyrrhiza Glabra (Licorice) Extract, Helianthus Annuus (Sunflower) oil, Ilex Paraguariensis (Yerba Mate') Extract, Isopropyl Myristate, Methylsulfonylmethane (MSM), Magnesium Sulfate, Pantothenic Acid (Vitamin B5), Pyridoxine (Vitamin B6), Salix Nigra (Willow) Bark Extract, Sodium Benzoate, Sorbitan Oliviate, Squalane, Tetrasodium EDTA, Tocopheryl Acetate (Vitamin E), Xanthan Gum, Zemea (Corn) Propanediol.

Package Labeling:

COOLING PAIN RELIEF
120ml (4 fl oz.)

**CBD INFUSED
TOPICAL LOTION**
500mg

REINA

DRUG FACTS

ACTIVE INGREDIENTS:	PURPOSE
Methyl Salicylate 10%.....	Topical Analgesic
Menthol 4%	Topical Analgesic

USES: Temporarily relieves inflammation, mild aches and pains of muscle joints.

WARNINGS:

- Only for external use.
- Do not use: on open wounds, cuts, damaged or infected skin as well as in the eyes, mouth, genitals, or any other mucous membranes.
- Consult your physician: if pain is persistent or worsens or if using any other topical pain products.
- Call poison control if swallowed. If contact with eyes occurs, rinse eyes thoroughly with cold water.

Keep out of reach of children. Consult physician for children under 12.

DIRECTIONS: (Store in a cool dry place)
Wash and dry affected area. Shake bottle well before each use and gently rub over area of pain. Use is not recommended more than four times a day. Wash hands immediately afterwards and avoid contact with eyes.

INACTIVE INGREDIENTS:
Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, C12-15 Alkyl Benzoate, Cannabis Sativus (Full Spectrum Hemp) Seed Oil, Capsaicin, Chamomilla Recutita (Chamomile) Extract, Cetearyl Oliviate, Cetyl Alcohol, Cetyl Myristoleate, Chondroitin Sulfate, Gluconolactone, Glucosamine Sulfate, Glycerin, Glyceryl Stearate, Glycyrrhiza Glabra (Licorice) Extract, Helianthus Annuus (Sunflower) oil, Ilex Paraguariensis (Yerba Mate') Extract, Isopropyl Myristate, Methylsulfonylmethane (MSM), Magnesium Sulfate, Pantothenic Acid (Vitamin B5), Pyridoxine (Vitamin B6), Salix Nigra (Willow) Bark Extract, Sodium Benzoate, Sorbitan Oliviate, Squalane, Tetrasodium EDTA, Tocopheryl Acetate (Vitamin E), Xanthan Gum, Zemea (Corn) Propanediol.

Manufactured for:
Reina Wellness - 4440 Arville St. Suite 31, Las Vegas, NV. 89103
reinawellness.com



REINA CBD INFUSED TOPICAL PAIN RELIEF

methyl salicylate, menthol lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73588-068
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	100 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAPSAICIN (UNII: S07O44R1ZM)	
CHAMOMILE (UNII: FGL3685T2X)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETYL MYRISTOLEATE (UNII: 87P8K33Q5X)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LICORICE (UNII: 61ZBX54883)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
PANTOTHENIC ACID (UNII: 19F5HK2737)	
SALIX NIGRA BARK (UNII: QU52J3A5B3)	

SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
SQUALANE (UNII: GW89575KF9)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CORN (UNII: 0N8672707O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73588-068-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/20/2020	

Labeler - Reina Wellness LLC (117245556)

Revised: 1/2020

Reina Wellness LLC