

**PROVAULT COOLING ROLL ON- menthol, camphor gel**  
**Sombra Cosmetics Inc**

*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.*

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**Provault Cooling Roll on**

**Active Ingredients**

Menthol USP 8%, Camphor USP 2%

**Purpose**

Purpose  
External Analgesic

**Keep out of reach of children**

Keep out of reach of children

**Uses**

Temporary relief of minor aches and pains of muscles and joints associated with strains, bruises and sprains.

**Warnings**

**For external use only.**

**Directions**

Apply to affected area not more than 3 to 4 times daily. After each application, wash hands with soap and water (unless applying to hands). Children under the age of 18, consult a doctor before use.

**Inactive Ingredients**

Aloe Baradensis (Aloe) Leaf Juice, Aqua/Purified Water, Arnica Montana (Arnica) Flower Extract, Cannabidiol (CBD), Chamomilla Recutita (Chamomile) Flower Extract, Gluconolactone, Glycerin (Kosher Vegetable), Hemp Seed Oil, Lonicera Japonica (Honeysuckle) Flower Extract, Mentha Arvensis (mint) Leaf Oil, Rosmarinus Officinalis (Rosemary) Leaf Oil, Tocopherol (Natural Vitamin E), Xanthan Gum.

## Questions or Comments

Call 866 419 0043

**TAKE YOUR GAME TO THE NEXT LEVEL**

PROVAULT products are consciously formulated with Hemp-Derived CBD and all-natural ingredients. CBD, or Cannabidiol, is one of over one hundred naturally occurring cannabinoids found in the Hemp plant and is recognized for its nourishing properties. PROVAULT CBD products are non-psychoactive.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease. This product contains less than 0.3% Delta-9 THC.

**PROVAULTCBD.COM**



**PROVAULT™**  
SPORTS PERFORMANCE FORMULAS

**COOLING ROLL-ON**  
PAIN RELIEF

WITH CAMPHOR AND MENTHOL

Hemp Derived  
**CBD**  
1500 mg  
THC-FREE

3 fl oz (88.7 mL)

Alleviate minor muscle aches and pains with PROVAULT Cooling Roll-On, a convenient, hands-free application that penetrates quickly. Camphor and Menthol blended with natural botanicals - including Hemp-CBD - offer a cooling effect in this signature, lightweight, fast-absorbing formula. Don't let sore muscles slow you down. Take your game to the next level with PROVAULT.

SCAN QR CODE FOR PRODUCT INFORMATION



MADE IN THE USA by:  
Lief Holdings LLC,  
9016 Fullbright Avenue,  
Chatsworth, CA 91311

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### Drug Facts

#### Active Ingredients Purpose

Camphor 2% ----- External Analgesic  
Menthol 8% ----- External Analgesic

#### Uses

Temporary relief of minor aches and pains of muscles and joints associated with strains, bruises, and sprains.

#### Warnings

**For external use only**  
Do not use on wounds or damaged skin

#### When using this product

avoid contact with eyes or mucous membranes do not bandage tightly or use with a heating pad

#### Stop use and ask a doctor if

condition worsens symptoms persist for more than 7 days symptoms clear up and occur again within a few days excessive skin irritation develops

**If pregnant or breast-feeding** ask a health professional before use. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

#### Directions

Apply to affected area not more than 3 to 4 times daily. After application, wash hands with soap and water (unless applying to hands). Children under the age of 18, consult a doctor before use.

#### Inactive Ingredients

Aloe barbadensis (Aloe) Leaf Juice\*, Aqua/Purified Water, Arnica montana (Arnica) Flower Extract\*, Cannabidiol (CBD), Chamomilla recutita matricaria (Chamomille) Flower Extract, Gluconolactone, Glycerin (Kosher Vegetable), Hemp Seed Oil\*, Lonicera caprifolium (Honeysuckle) Flower Extract, Lonicera japonica (Honeysuckle) Flower Extract, Mentha arvensis (Mint) Leaf Oil\*, Rosmarinus officinalis (Rosemary) Leaf Oil\*, Tocopherol (Natural Vitamin E)\*, Xanthan Gum \*Certified Organic

**Questions?** Call 866 419 0043

## PROVAULT COOLING ROLL ON

menthol, camphor gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61577-6100
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.08 g in 1 g
<b>CAMPHOR (NATURAL)</b> (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	.02 g in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CANNABIDIOL</b> (UNII: 19GBJ60SN5)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>ARNICA MONTANA FLOWER WATER</b> (UNII: U7L2JP51PR)	
<b>ROSEMARY OIL</b> (UNII: 8LGU7VM393)	
<b>CHAMOMILE</b> (UNII: FGL3685T2X)	
<b>HEMP</b> (UNII: TD1MUT01Q7)	
<b>LONICERA JAPONICA FLOWER</b> (UNII: 4465L2WS4Y)	
<b>MENTHA ARVENSIS FLOWER OIL</b> (UNII: Q129Z1W6Y2)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:61577-6100-1	88.7 g in 1 BOTTLE; Type 0: Not a Combination Product	10/19/2022	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part348	10/19/2022	

**Labeler** - Sombra Cosmetics Inc (097464309)

## Establishment

Name	Address	ID/FEI	Business Operations
Sombra Cosmetics		097464309	manufacture(61577-6100) , label(61577-6100)

Revised: 10/2022

Sombra Cosmetics Inc