

**CANNASERENE HOT AND COLD CBD CREAM- hot and cold cream cream**  
**BioSerene 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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**CannaSerene Hot & Cold CBD Cream**

**Active Ingredients**

# *Drug Facts*

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<i>Active Ingredients</i>	<i>Purpose</i>
Menthol 10%.....	Topical Analgesic
Methyl Salicylate 4%.....	Topical Analgesic

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**Uses**

Temporary relief from minor aches and pains of sore muscles and joints associated with: arthritis, backaches, strains, bruises, sprains, and pulled muscles.

**Purpose**

Topical Analgesic

**Directions**

- Adults and children 12 years of age and older: Massage over affected areas no more than 3 to 4 times daily. Wash hands after use.
- Children under 12 years of age: consult a doctor.

**Warnings**

FOR EXTERNAL USE ONLY.

Flammable. Keep away from fire or flame.

Allergy Alert. If prone to allergic reaction from aspirin or salicylates, consult doctor before use.

### **Do Not Use**

Do not use on wounds or damaged skin or with a heating pad.

### **When Using This Product**

- Use only as directed
- Avoid contact with eyes or mucous membranes
- Do not bandage tightly

### **Stop Use and Ask a Doctor**

- If condition worsens
- Symptoms persist more than 7 days or clear up and occur again within a few days
- Excessive skin irritation develops.

### **Keep Out of Reach of Children**

If swallowed, get medical help or contact a Poison Control Center immediately.

### **Storage and Handling**

Store at controlled room temperature 20°-25°C (68°-77°F). Keep away from direct sunlight.

### **Inactive Ingredients**

Purified Water, Menthol, Gaultheria Procumbens (Wintergreen) Leaf Oil, Fractionated Coconut Oil, Polysorbate 80, Sorbitan Stearate, Cetearyl Alcohol, Isopropyl Myristate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Cannabidiol, Dimethyl Isosorbide, Oenothera Biennis (EveningPrimrose) Oil, Tocopherol Acetate (VitaminE), Propylene Glycol, Diazolidinyl Urea, Iodopropynyl Butylcarbamate

### **Labeling**

#### **CannaSerene Hot & Cold CBD Cream - For Tired Joints & Muscles**

**CBD 1200MG** (for 100mL)

*CBD Isolate 12mg/ml*

- Made in USA
- Formulated By a Pharmacist
- cGMP Certified

**Manufactured By:** BioSerene, Inc.

4398 SW Port Way, Palm City, FL 34990 USA

### Drug Facts

**Active Ingredients Purpose**  
Menthol 10%.....Topical Analgesic  
Methyl Salicylate 4%.....Topical Analgesic

**Uses:** Temporary relief from minor aches and pains of sore muscles & joints associated with: arthritis, backache, strains, bruises, and sprains.

**Warnings:** For external use only.  
**Flammable:** Keep away from fire or flame. **Allergy Alert:** If prone to allergic reaction from aspirin or salicylates, consult doctor before use.

**Do not use** • on wounds or damaged skin • with a heating pad



Manufactured By: BioSerene, Inc.  
4398 SW Port Way, Palm City, FL 34990



NDC: 74787-1801-3

CannaSerene

# HOT & COLD CBD CREAM

FOR TIRED JOINTS & MUSCLES

FORMULATED BY A PHARMACIST



**CBD 1200MG**  
CBD ISOLATE 12mg/mL  
Topical Analgesic Cream  
100 ml (3.4 fl oz)

### Drug Facts (continued)

**When using this product** • use only as directed • avoid contact with eyes or mucous membranes • do not bandage tightly

**Stop use and ask a doctor if**  
• condition worsens • symptoms persist more than 7 days or 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

• Adults and children 12 years of age and older: Massage over affected areas no more than 3 to 4 times daily. Wash hands after use.  
• Children under 12 years of age: Consult a doctor.

#### Other Information

Store at controlled room temperature 20°-25°C (68°-77°F)

#### Inactive Ingredients

Purified Water, Fractionated Coconut Oil, Polysorbate 80, Sorbitan Stearate, Cetearyl Alcohol, Isopropyl Myristate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Cannabidiol (Hemp Derived CBD), Dimethyl Isosorbide, Oenothera Biennis (Evening Primrose) Oil, Tocopherol Acetate (Vitamin E), Propylene Glycol, Diazolidinyl Urea, Iodopropynyl Butylcarbamate

## CANNASERENE HOT AND COLD CBD CREAM

hot and cold cream cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74787-1801
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	4 g in 100 mL
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%)</b> (UNII: 86FQE96TZ4)	

<b>CANNABIDIOL</b> (UNII: 19GBJ60SN5)				
<b>DIMETHYL ISOSORBIDE</b> (UNII: SA6A6V432S)				
<b>EVENING PRIMROSE OIL</b> (UNII: 3Q9L08K71N)				
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74787-1801-3	100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/14/2022	01/20/2025
2	NDC:74787-1801-2	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/14/2022	01/20/2025
3	NDC:74787-1801-0	10 mL in 1 TUBE; Type 0: Not a Combination Product	06/14/2022	01/20/2025
<b>Marketing Information</b>				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part348	06/14/2022	01/20/2025

**Labeler -** BioSerene Inc. (117473724)

## Establishment

Name	Address	ID/FEI	Business Operations
BioSerene Inc.		117473724	manufacture(74787-1801)

Revised: 5/2023

BioSerene Inc.