

EXALTHEMP HOT AND COLD PAIN CREAM- hot and cold pain 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.

ExaltHemp Hot & Cold Pain Cream

Active Ingredients

Menthol 10%, Methyl Salicylate 4%

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

ExaltHemp Hot & Cold Pain Cream - For Tired Joints & Muscles

Hemp Extract 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

NDC: 74787-1901-3



HOT & COLD PAIN CREAM

FOR TIRED JOINTS & MUSCLES

PHARMACIST-FORMULATED

- ✓ FAST ABSORBING
- ✓ CALMING, WARMING, COOLING
- ✓ LONG-LASTING RELIEF

HEMP EXTRACT 1200MG (12 MG/ML)
Topical Analgesic Cream
100 ml (3.4 fl oz)

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



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, Hemp Extract Isolate, Dimethyl Isosorbide, Oenothera Biennis (Evening Primrose) Oil, Tocopherol Acetate (Vitamin E), Propylene Glycol, Diazolidinyl Urea, Iodopropynyl Butylcarbamate

EXALTHEMP HOT AND COLD PAIN CREAM

hot and cold pain cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74787-1901
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
CANNABIDIOL (UNII: 19GBJ60SN5)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74787-1901-3	100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/23/2022	01/20/2025
2	NDC:74787-1901-2	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/23/2022	01/20/2025
3	NDC:74787-1901-0	10 mL in 1 TUBE; Type 0: Not a Combination Product	06/23/2022	01/20/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/23/2022	01/20/2025

Labeler - BioSerene Inc. (117473724)

Establishment

Name	Address	ID/FEI	Business Operations
BioSerene Inc.		117473724	manufacture(74787-1901)

Revised: 5/2023

BioSerene Inc.