

PROVAULT MUSCLE CREAM CBD- menthol, camphor cream
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.

Provault Muscle Cream CBD

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

Alchemilla Vulgaris (Lady's Mantle) Extract, Allantoin, Aloe Barbadensis (Aloe) Leaf Juice, Aqua/Purified Water, Arnica Montana (Arnica) Flower Extract, Butyrospermum Parkii (Shea) Butter, Cannabidiol (CBD), Caprylic/Capric Triglyceride, Cetearyl Glucoside, Cetyl Alcohol, Chamomilla Recutita Matricaria (Chamomile) Flower Extract, Citrus medica Limon (Lemon) Peel Oil, Eucalyptus Globulus Leaf Oil, Gluconolactone, Glycerin (Kosher Vegetable), GLyceryl Sterate SE, Hemp Seed Oil, Lonicera Japonica (Honeysuckle) Flower Extract, Mentha Arvensis (mint) Leaf Oil, Olea Europaea (Olive) Fruit Oil, Rosmarinus

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CANNABIDIOL (UNII: 19GBJ60SN5)	
TOCOPHEROL (UNII: R0ZB2556P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
SHEA BUTTER (UNII: K49155WL9Y)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
LEMON OIL (UNII: I9GRO824LL)	
CHAMOMILE (UNII: FGL3685T2X)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
hemp (UNII: TD1MUT01Q7)	
MENTHA ARVENSIS FLOWER OIL (UNII: Q129Z1W6Y2)	
ARNICA MONTANA FLOWER WATER (UNII: U7L2JP51PR)	
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	
CAPRYLIC/CAPRIC/LINOLEIC TRIGLYCERIDE (UNII: U73D397055)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-6200-1	88.7 g in 1 TUBE; Type 0: Not a Combination Product	10/18/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/18/2022	

Labeler - Sombra Cosmetics Inc (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
Sombra Cosmetics Inc		097464309	manufacture(61577-6200) , label(61577-6200)

