

PROVAULT MUSCLE SALVE- 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.

Provault Muscle Salve

Active Ingredients

Menthol USP 7%, 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

Arnica Montana (Arnica) Flower Extract, Butyrospermum Parkii (Shea) Butter, Calendula officinalis (Calendula) Flower Extract, Cannabidiol (CBD), Chamomilla Recutita Matricaria (Chamomile) Flower Extract, Citrus Medica Limonum (Lemon) Peel Oil, Eucalyptus Globulus Leaf Oil, Glycerin, (Kosher Vegetable), Hemp Seed Oil, Hydrogenated Cocos Nucifera (Coconut) Oil, Lonicera Japonica (Honeysuckle) Flower Extract, Mentha Avensis (Mint) Leaf Oil.

Questions or Comments

Call 866 419 0043

<p>Drug Facts (continued)</p> <p>Inactive Ingredients Arnica montana (Arnica) Flower Extract*, Butyrospermum parkii (Shea) Butter, Calendula officinalis (Calendula) Flower Extract, Cannabidiol (CBD), Chamomilla recutita matricaria (Chamomile) Flower Extract, Citrus medica limonum (Lemon) Peel Oil*, Eucalyptus globulus Leaf Oil*, Glycerin (Kosher Vegetable), Hemp Seed Oil*, Hydrogenated cocos nucifera (Coconut) Oil, Lonicera caprifolium (Honeysuckle) Flower Extract, Lonicera japonica (Honeysuckle) Flower Extract, Mentha arvensis (Mint) Leaf Oil*,</p>	<p>Drug Facts (continued)</p> <p>Inactive Ingredients (continued) Oryza sativa (Rice) Extract, Rosmarinus officinalis (Rosemary) Leaf Oil*, Simmondsia chinensis (Jojoba) Seed Oil, Tocopherol (Natural Vitamin E)* *Certified Organic</p> <p>Questions? Call 866.419.0043</p>	
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PROVAULT MUSCLE SALVE

menthol, camphor gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-6300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.07 g in 1 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	.02 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
SHEA BUTTER (UNII: K49155WL9Y)	
HYDROGENATED COCONUT OIL (UNII: JY81OXM1OM)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CANNABIDIOL (UNII: 19GBJ60SN5)	
TOCOPHEROL (UNII: R0ZB2556P8)	
JOJOBA OIL (UNII: 724GKU717M)	
ARNICA MONTANA FLOWER WATER (UNII: U7L2JP51PR)	
HEMP (UNII: TD1MUT01Q7)	
LEMON OIL (UNII: I9GRO824LL)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

SPEARMINT OIL (UNII: C3M81465G5)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-6300-1	68 g in 1 JAR; Type 0: Not a Combination Product	10/19/2022	

Marketing Information

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

Labeler - Sombra Cosmetics Inc (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
Sombra Cosmetics Inc		097464309	manufacture(61577-6300) , label(61577-6300)

Revised: 10/2022

Sombra Cosmetics Inc