PROVAULT DRYSPRAY CBD PAIN RELIEF- menthol, camphor spray 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 DrySpray CBD Pain Relief

Active Ingredients

Menthol USP 9%, Camphor USP 2%

Purpose

Purpose External Analgesic

Keep out of reach of children

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Uses

Temporary relief of monor 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.

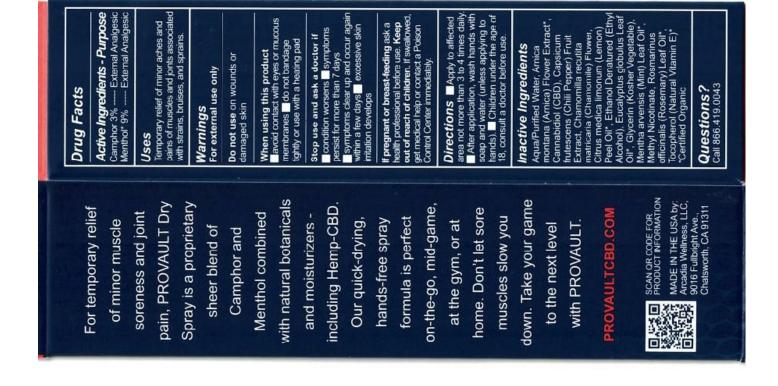
Inactive Ingredients

Aqua/Purified water, Arnica Montana (arnica) Flower Extract, Cannabidiol (CBD), Capsicum Frutescens (Chili Pepper) Friut Extract, Chamomilla Recutita Matricaria (Chamomile) Flower, Citrus medica Limonum (Lemon) Peel Oil, Ethanol Denatured (Ethyl Alcohol), Eucalyptus Globulus Leaf Oil, Glycerin (Kosher Vegetable), Mentha Avensis (Mint) Leaf Oil, Metyl Nicotinate, Rosmarinus Officinalis (Rosemary) Leaf Oil, Tocopherol (Natural Vitamin E).

Questions or Comments

Call 866 419 0043





menthol, camphor spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-6000	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.09 g in 1 g	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	.02 g in 1 g	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
CANNABIDIOL (UNII: 19GBJ60SN5)			
CAPSAICIN (UNII: S07044R1ZM)			
TOCOPHEROL (UNII: ROZB2556P8)			
ROSEMARY OIL (UNII: 8LGU7VM393)			
LEMON OIL (UNII: 19GRO824LL)			
CHAMOMILE (UNII: FGL3685T2X)			
ALCOHOL (UNII: 3K9958V90M)			
EUCALYPTUS OIL (UNII: 2R04ONI662)			
MENTHA ARVENSIS FLOWER OIL (UNII: Q129Z1W6Y2)			
ARNICA MONTANA FLOWER WATER (UNII: U7L2JP51PR)			
METHYL NICOTINATE (UNII: 7B1AVU9DJN)			

l	Packaging				
	#	Item Code Package Description		Marketing Start Date	Marketing End Date
	1	NDC:61577- 6000-1	88.7 g in 1 BOTTLE; 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	

Establishment				
Name	Address	ID/FEI	Business Operations	
Sombra Cosmetics Inc		097464309	manufacture(61577-6000) , label(61577-6000)	

Revised: 10/2022 Sombra Cosmetics Inc