TRUVITALITY CBD MUSCLE FREEZE 4% MENTHOL- menthol gel TRUVITALITY, LLC

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.

TruVitality CBD Muscle Freeze Roll-On

Menthol 4%.

Adults and children over 2 years: Rub a thin film over affected areas up to 4 times daily. Children under 2 years: Consult a physician.

Warnings: For external use only.

When using this product: Use only as directed. Do not bandage tightly. Do not use a heating pad or device. Avoid contact with the eyes and mucous membranes. Do not apply to wounds or damaged, broken or irritated skin. Do not use with other ointments.

Flammable: Keep away from excessive heat or flame.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Aloe Juice, Cannabidiol (Hemp Derived, THC-Free), Carbomer, Glycerin, MCT Coconut Oil, PhenoxyEthanol, Propylene Glycol, Water.

Uses: Menthol provides temporary relief from minor aches and pains of sore muscles & joints associated with: simple backache, strains, sprains, bruises, cramps.

Keep out of reach of children. If accidentally ingested, get medical help or contact a Poison Control Center immediately at 1-800-222-1222.

Menthol 4%: Cooling Pain Relief.

Stop use and ask a doctor if: Condition worsens, irritation develops, symptoms persist for over 7 days or clear up and reoccur within a few days.

If pregnant or breast-feeding: Ask a health professional before use.

Do not freeze. Keep lid tightly closed when not in use. Store in a cool place.

Questions or Comments?: 1-800-214-4064.



TRUVITALITY CBD MUSCLE FREEZE 4% MENTHOL

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73155-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10 EIP3A) (MENTHOL, UNSPECIFIED FO UNII:L7T10 EIP3A)	RM - MENTHOL, UNSPECIFIED FORM	4 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
PHENO XYETHANOL (UNII: HIE492ZZ3T)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
ALOE (UNII: V5VD430 YW9)		
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0KO0R)		
CARBO XYPO LYMETHYLENE (UNII: 0 A5MM30 7FC)		
CANNABIS SATIVA SUBSP. SATIVA WHOLE (UNII: 0 XTN3895NP)		

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:73155-004-	1 in 1 BOX	0 1/30/20 20	
	1	3 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/30/2020	

Labeler - TRUVITALITY, LLC (117075021)

Establishment			
Name	Address	ID/FEI	Business Operations
Deenterprises, Inc.		073070083	manufacture(73155-004), pack(73155-004), label(73155-004)

Revised: 12/2019 TRUVITALITY, LLC