

CBD UNLIMITED TOPICAL ANALGESIC- menthol and camphor spray
ENDEXX CORPORATION

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.

CBD UNLIMITED BODY SPRAY

Active ingredient

Menthol USP 5%

Camphor 3.25%

Purpose

Topical Analgesic

Uses

Temporary relief from minor aches and pains of muscles & joints associated with: arthritis, simple backache, strains, sprains

Warnings:

For external use only.

When using this product:

- use only as directed
- do not bandage tightly or use with a heating pad
- avoid contact with eyes and mucous membranes
- do not apply to wounds or damaged, broken or irritated skin
- do not spray onto face
- avoid inhaling spray mist and fumes

Stop use and ask doctor if:

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clears up and occurs again within a few days

Flammable

☐ **do not use near** heat or open flame or while smoking

If pregnant or breast-feeding, ask a healthcare professional before use

Keep Out of Reach of Children

If product is swallowed get medical help or contact a Poison Control Center right away.

Directions:

FOR EXTERNAL USE ONLY:

Shake Before Using

Adults and children 12 years of age and older:

Spray on affected areas 1 to 4 times daily.

Avoid contact with eyes and mouth.

Inactive Ingredients

Arnica Extract (Glycerin, Water, Arnica Montana Flower Extract), Clove Bud Oil, Eucalyptus Globulus Leaf Oil, Hemp-Derived Cannabidiol Isolate, Isopropyl Alcohol, Methylsulfonylmethane (MSM), Wintergreen Oil (Methyl Salicylate)

Principal Display Panel

Match to PMS 637cp

2.25" x 1.375" x 4.25"
Flat - 10.75" x 7.3"

Adhesive Strips

Hemp Industry Leaders Since 2014

Drug Facts	
Active Ingredients	Purpose
Menthol, USP 5%.....	Topical Analgesic
Camphor, USP 3.25%.....	Topical Analgesic

Uses: For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, backache, strains and sprains.

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3.5" x 1.5"



Match to PMS 2391cp

Match to PMS 637cp

CBD UNLIMITED TOPICAL ANALGESIC

menthol and camphor spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73045-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	50 mg in 1 mL
CAMPHOR OIL (UNII: 75IZZ8 Y727) (CAMPHOR OIL - UNII:75IZZ8 Y727)	CAMPHOR OIL	325 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

CLOVE OIL (UNII: 578389D6D0)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
Dimethyl Sulfone (UNII: 9H4PO4Z4FT)	
GAULTHERIA PRO CUMBENS LEAF (UNII: 2125M16OWN)	
Cannabidiol (UNII: 19GBJ60SN5)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73045-004-01	15 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/05/2020	
2	NDC:73045-004-02	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/05/2020	
3	NDC:73045-004-03	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/05/2020	

Labeler - ENDEXX CORPORATION (002119594)

Registrant - ENDEXX CORPORATION (002119594)

Establishment

Name	Address	ID/FEI	Business Operations
Velocity Production and Packaging		081076893	manufacture(73045-004)