

CBD UNLIMITED BALMX TOPICAL ANALGESIC- menthol cream
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 BALMX TOPICAL ANALGESIC

Active ingredient

Menthol 1.25%

Purpose

Topical Analgesic

Inactive ingredients

Arnica Oil, Beeswax, Clove Bud Oil, Grapeseed Oil, Hemp Isolate, Hemp Seed Oil, Lavender Oil, MSM (Methylsulfonylmethane), MCT Coconut Oil, Organic Lemongrass Oil, Organic Moringa Oil, Sweet Birch Oil.

Uses

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

Warnings:

For external use only.

Do not use on wounds or damaged skin.

When using this product: Avoid contact with the eyes. Do not bandage tightly.

Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breast-feeding ask a health 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:

Adults and children 12 years of age & older. Rub well on affected area not more than 3 to 4 times daily. For children 12 years or younger, consult a doctor before use.

Distributed By:




CBD UNLIMITED INC


Principal Display Panel

CBD UNLIMITED BALMX

TOPICAL ANALGESIC

2 fl. oz. (60mL) Balm

<p>Hemp Industry Leaders Since 2014</p> <p>Controlled Production Process</p> <p>Scientifically Formulated</p> <p>Learn More At: CBDUNLIMITED.COM</p> <p>FOR EXTERNAL USE ONLY</p>	 <p>BALMX</p> <p>TOPICAL ANALGESIC</p> <p>FOR EXTERNAL USE ONLY</p> <p>2oz. (60mL)</p>	<p>Drug Facts</p> <table border="1"> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> <tr> <td>Menthol USP 1.25%</td> <td>Topical Analgesic</td> </tr> </table> <p>Uses: Temporary relief from minor aches and pains of muscles & joints associated with: arthritis • simple backache • strains • sprains</p> <p>Warnings: For external use only. Do not use on wounds or damaged skin.</p> <p>When using this product: • avoid contact with the eyes • do not bandage tightly</p> <p>Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions: Adults and children 12 years of age & older, Rub well on affected areas not more than 3 to 4 times daily. • For children 12 years or younger, consult a doctor before use.</p> <p>Other Information: This product may cause an allergic reaction for some individuals. Test on small area before use.</p> <p>Inactive Ingredients: Arnica Oil, Stearic Acid, Olive Bud Oil, Grapeseed Oil, Hemp Isolate, Hemp Seed Oil, Lavender Oil, Menthol, Benzocaine (MSB), MCT Coconut Oil, Organic Lemongrass Oil, Organic Moringa Oil, Sweet Birch Oil.</p>	Active Ingredients	Purpose	Menthol USP 1.25%	Topical Analgesic	<p>1000mg PREMIUM HEMP ISOLATE</p>  <p>U.S. Grown Hemp. Manufactured In The USA.</p> <p>DIST. BY: CBD UNLIMITED, INC. Cave Creek, Arizona 85331 cbdunlimited.com 480.999.0097</p> 
Active Ingredients	Purpose						
Menthol USP 1.25%	Topical Analgesic						

<p>DIRECTIONS: Adults and children over 12 years of age & older. Rub well on affected areas not more than 3 to 4 times daily. For children 12 years or younger, consult a doctor before use.</p> <p>U.S. Grown Hemp. Manufactured In America.</p>	<p>FOR EXTERNAL USE ONLY</p>  <p>BALMX</p> <p>TOPICAL ANALGESIC</p> <p>2oz. (60mL)</p>	<p>CBD UNLIMITED, INC. Cave Creek, AZ 85331 480-999-0097 cbdunlimited.com</p>	<table border="1"> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> <tr> <td>Menthol USP 1.25%.....</td> <td>Topical Analgesic</td> </tr> </table> <p>1000mg Hemp Isolate</p> 	Active Ingredients	Purpose	Menthol USP 1.25%.....	Topical Analgesic
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CBD UNLIMITED BALMX TOPICAL ANALGESIC

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73045-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.25 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
HEMP (UNII: TD1MUT01Q7)	
CLOVE OIL (UNII: 578389D6D0)	
COCONUT OIL (UNII: Q9L0O73W7L)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	

CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
MORINGA OLEIFERA SEED OIL (UNII: REM6A5QMC0)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73045-001-01	60 mL in 1 JAR; Type 0: Not a Combination Product	04/11/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/11/2019	

Labeler - ENDEXX CORPORATION (002119594)

Registrant - ENDEXX CORPORATION (002119594)

Revised: 1/2021

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