

MAGNIFICENT MENTHOL WARMING CREAM- menthol cream cream
RENU LABORATORIES, 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.

MagNificent Menthol Warming Pain Cream

Active Ingredient:

Menthol 5%

Topical Analgesic

Warnings

For external use only

When using this product

Do not bandage tightly

- avoid contact with eyes
- do not apply to wounds or damaged skin
- do not use with heating pads or other heating devices.

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

Keep out of reach of children

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

Directions

adults and children 12 years of age and older, apply to affected area no more than 10 times a day or as directed by your physical or occupational therapist.

children under 12 years of age: consult your physical or occupational therapist.

Directions

- adults and children 12 years of age and older, apply to affected area no more than 10 times a day or as directed by your physical or occupational therapist.
- children under 12 years of age: consult your physical or occupational therapist.

Inactive Ingredients:

Butyrospermum Parkii (Shea) Butter, Cannabis Sativa (Hemp) Seed Oil and Hemp Oil and Hemp Derived Cannabidiol (CBD) Extract, Capsicum Frutescens Fruit Extract, Cetearyl Alcohol, Cetearyl Glucoside, Citrus Paradisi (Grapefruit) Extract, Cocos Nucifera (Coconut) Oil, Deionized Water, Emulsifying Wax, Hamamelis Virginiana (Witch Hazel),

Magnesium Chloride, Mangifera Indica (Mango) Seed Butter, Mentha Piperita (Peppermint) Leaf Oil, Olea Europaea (Olive) Oil, Olus Oil (Vegetable), Phenoxyethanol, Xanthan Gum

Manufactured for:

X12LLC West Chester, PA 19380

www.Magx12.com

for temporary relief of minor aches and pains of muscles and joints associated with deep muscle therapy treatments

MAGNIFICENT_warming_Layered_Label_FINALCorrected (2).jpg

Magnificent_Round_Warming_CBD (2).jpg

Magnificent-WARMING CBD_ART_Box_112718 (2).jpg



Magnificent_Round_Warming_CBD (2).jpg

Be Well
Magnificently



Massage **Magnificent Menthol Warming Pain Cream** into sore muscles & joints to help relieve pain. Use as often as needed. Feel the warming effect upon application.

Magnificent[®]
EveryBODY Needs Magnesium.

Menthol Warming Pain Cream

Menthol, Magnesium,
Hemp Seed & CBD Oils
(THC Free)

Net Wt. 4oz.



Magnesium along with CBD is a powerful combination of anti-inflammatory agents working to help relieve pain in any muscles & joints.

Manufactured for:
X12 LLC West Chester PA 19380
www.Magn12.com

Drug Facts	Active Ingredient: Menthol 5%	Purpose: Topical Anesthetic
Uses: For temporary relief of minor aches and pains of muscles and joints associated with deep muscle therapy treatments.		
Warnings: For external use only.		
When using this product: Do not bandage tightly - avoid contact with eyes - do not apply to wounds or damaged skin - do not use with heating pads or other heating devices.		
Stop use and ask a doctor if: Condition worsens or if symptoms persist for more than 7 days or come up and occur again within a few days.		
Keep out of reach of children: If swallowed, get medical help or contact a Poison Control Center right away.		
Directions: Adults and children 12 years of age and older: apply to affected area no more than 10 times a day or as directed by your physical or occupational therapist - children under 12 years of age: consult your physical or occupational therapist.		
Active Ingredients: Butyrospermum Parvif (Shea Butter), Carnauba (Carnauba) Wax, Cetyl Alcohol, Cetyl Myristate, Citrus Paradii (Grapefruit) Extract, Cocos Nucifera (Coconut) Oil, Dalbergia Sissoo (Rosewood) Extract, Emulsifying Wax, Hamamelis Virginiana (Witch Hazel), Magnesium Chloride, Mangifera Indica (Mango) Seed Butter, Mentha Piperita (Peppermint) Leaf Oil, Olea Europaea (Olive) Oil, Ocus Oil (Vegetable), Phenoxyethanol, Xanthan Gum		



TOP

1.25 inches

Manufactured for:
X12 LLC West Chester PA 19380
www.Magx12.com

MagNificent®
EveryBODY Needs Magnesium.

Menthol Warming Pain Cream

Menthol, Magnesium,
Hemp Seed & CBD Oils

Magnesium along with CBD is a powerful combination of anti-inflammatory agents working to help relieve pain in any muscles & joints.

Net Wt. 4oz.

Lift for Drug Facts label

7 inches

INSIDE TOP

<p>Drug Facts</p> <p>Active ingredient: Menthol 5%</p> <p>Purpose: Topical Analgesic</p> <p>Uses: for temporary relief of minor aches and pains of muscles and joints associated with deep muscle therapy treatments.</p>	<p>Warnings For external use only</p> <p>When using this product Do not bandage tightly - avoid contact with eyes - do not apply to wounds or damaged skin - do not use with heating pads or other heating devices.</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</p> <p>Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.</p>	<p>Directions • adults and children 12 years of age and older, apply to affected area no more than 10 times a day or as directed by your physical or occupational therapist. • children under 12 years of age, consult your physical or occupational therapist.</p>
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BASE

Inactive Ingredients:
Butyrospermum Parkii (Shea Butter), Cannabis Sativa (Hemp) Seed Oil and Hemp Derived Cannabidiol (CBD) Extract, Capsicum Frutescens Fruit Extract, Cetearyl Alcohol, Cetearyl Glucoside, Citrus Paradisi (Grapefruit) Extract, Cocos Nucifera (Coconut) Oil, Deionized Water, Emulsifying Wax, Hamamelis Virginiana (Witch Hazel) Magnesium Chloride, Mangifera Indica (Mango) Seed Butter, Mentha piperita (Peppermint) Leaf Oil, Olea Europaea (Olive) Oil, Olus Oil (vegetable), Phenoxyethanol, Xanthan Gum

Manufactured for:
X12 LLC West Chester, PA 19380
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MAGNIFICENT MENTHOL WARMING CREAM

menthol cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-422
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.6 g in 112 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
SHEA BUTTER (UNII: K49155WL9Y)	
COCONUT OIL (UNII: Q9L0O73W7L)	
MANGIFERA INDICA SEED BUTTER (UNII: 40XD9M35X2)	

OLIVE OIL (UNII: 6UYK2W1W1E)
CANNABIDIOL (UNII: 19GBJ60SN5)
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)
CORN OIL (UNII: 8470G57WFM)
WHITE WAX (UNII: 7G1J5DA97F)
PEPPERMINT OIL (UNII: AV092KU4JH)
CAPSICUM (UNII: 00UK7646FG)
GRAPEFRUIT OIL (UNII: YR377U58W9)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
WITCH HAZEL (UNII: 101I4J0U34)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
LAURETH-7 (UNII: Z95S6G8201)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-422-02	1 in 1 BOX	02/18/2019	
1	NDC:76348-422-01	112 g in 1 JAR; 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	02/18/2019	

Labeler - RENU LABORATORIES, INC. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
Renu Laboratories, Inc.		945739449	manufacture(76348-422)

Revised: 1/2022

RENU LABORATORIES, INC.