

MAGNIFICENT MENTHOL COOLING PAIN CREAM- menthol topical analgesic 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 Cooling Pain Cream

Active Ingredient

Menthol 5%

Purpose

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: contact physical or occupational therapist

Inactive Ingredients:

Butyrospermum Parkii (Shea Butter), Cannabis Sativa (Hemp) Seed Oil and Hemp Derived Cannabidiol (CBD) 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

TOP

1.25 inches

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



MagNificent®

EveryBODY Needs Magnesium.

Menthol Cooling 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.



7 inches

INSIDE TOP

Drug Facts	Warnings For external use only	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	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 ingredient: Menthol 5%	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.	Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.	
Purpose: Topical Analgesic			
Uses: For temporary relief of minor aches and pains of muscles and joints associated with deep muscle therapy treatments.			

BASE

Inactive Ingredients:

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Manufactured for:
X12 LLC West Chester, PA 19380
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DEADNER

Just a place holder

RELEASE





Drug Facts

Active ingredient: Menthol 5% **Purpose:** Topical Analgesic

Uses: For temporary relief of minor aches and pains of muscles and joints associated with deep muscle therapy treatments.

Warnings: For external use only.

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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.

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Inactive ingredients: Butyrospermum Parkii (Shea Butter), Cannabis Sativa (Hemp) Seed Oil and Hemp Derived Cannabidiol (CBD) Extract, Cetylalyl Alcohol, Cetylalyl 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, Ocus Oil (Vegetable), Phenoxethanol, Xanthan Gum

Uses

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

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.



MAGNIFICENT MENTHOL COOLING PAIN CREAM

menthol topical analgesic cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-421
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
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
CORN OIL (UNII: 8470G57WFM)	

MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)
LAURETH-7 (UNII: Z95S6G8201)
SHEA BUTTER (UNII: K49155WL9Y)
XANTHAN GUM (UNII: TTV12P4NEE)
WHITE WAX (UNII: 7G1J5DA97F)
WITCH HAZEL (UNII: 101I4J0U34)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
PEPPERMINT OIL (UNII: AV092KU4JH)
GRAPEFRUIT OIL (UNII: YR377U58W9)
CANNABIDIOL (UNII: 19GBJ60SN5)
WATER (UNII: 059QF0KO0R)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
COCONUT OIL (UNII: Q9L0O73W7L)
OLIVE OIL (UNII: 6UYK2W1W1E)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-421-01	112 g in 1 JAR; Type 0: Not a Combination Product	12/06/2018	
2	NDC:76348-421-02	112 g in 1 BOX; Type 0: Not a Combination Product	12/06/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/06/2018	

Labeler - Renu Laboratories, Inc. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
Renu Laboratories, Inc.		945739449	manufacture(76348-421)