

MAG 5 PT WARMING FORMULA- menthol 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.

MAG 5 PT WARMING FORMULA RECOVERY CREAM

Menthol 5%

Topical Analgesic

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

For external use only

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

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, do not use, consult a doctor.

Arnica Montana (Arnica) Flower Extract, Butyrospermum Parkii (Shea) Butter, Cannabis Sativa (Hemp) Seed Oil, Cetearyl Alcohol, Cetearyl Glucoside, Cocos Nucifera (Coconut) Oil, Deionized Water, Emulsifying Wax, Fragrance, Hamamelis Virginiana (Witch Hazel), Hemp Derived Cannabidiol (CBD) Extract, Laureth-7, Lobelia Inflata (Lobelia) Extract, Magnesium Chloride, Magnesium Citrate, Magnesium Gluconate, Magnesium Myristate, Magnesium Sulfate, Mangifera Indica (Mango) Seed Buter, Mentha Piperita (Peppermint) Oil, Olea Europaea (Olive) Oil, Olus Oil (Vegetable), Phenoxyethanol, Polyacrylamide C13-14 Isoparaffin, Xanthan Gum

TOP

4oz

1.25 inches

Magnesium 5
Magnesium Chloride
Magnesium Glycinate

Effectively relaxes tight muscles, relieves stress, improves sleep, and supports overall health. Contains 500mg of Magnesium per serving. Use as Directed.

Use as Directed

7 inches

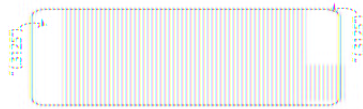
INSIDE TOP

| | | | |
|---|--|--|---|
| Drug Facts Active ingredient: Magnesium | Warnings: For oral use only. | Steps and ask a doctor if: • Continue symptoms • Symptoms worsen or do not improve • You are pregnant or breastfeeding • You are taking other medicines | Directions: • Take one (1) tablet twice daily with meals. • Do not take more than the recommended dose. • Do not take if you are pregnant or breastfeeding. |
| Purpose: To help relieve muscle tension and promote relaxation. | When using this product: • Do not take if you are pregnant or breastfeeding. • Do not take if you are taking other medicines. | Keep out of reach of children: • Keep out of reach of children. • Do not use if the seal is broken or the container is damaged. | |
| Uses: • To help relieve muscle tension and promote relaxation. | | | |

BASE

| | |
|--|---|
| Inactive Ingredients: Dibutyltin Dilaurate, Polyethylene Glycol 400, Polyethylene Glycol 600, Polyethylene Glycol 800, Polyethylene Glycol 1000, Polyethylene Glycol 1500, Polyethylene Glycol 2000, Polyethylene Glycol 3000, Polyethylene Glycol 4000, Polyethylene Glycol 6000, Polyethylene Glycol 8000, Polyethylene Glycol 10000, Polyethylene Glycol 15000, Polyethylene Glycol 20000, Polyethylene Glycol 30000, Polyethylene Glycol 40000, Polyethylene Glycol 60000, Polyethylene Glycol 80000, Polyethylene Glycol 100000, Polyethylene Glycol 150000, Polyethylene Glycol 200000, Polyethylene Glycol 300000, Polyethylene Glycol 400000, Polyethylene Glycol 600000, Polyethylene Glycol 800000, Polyethylene Glycol 1000000. | Manufactured by: MAGNITUDE PHARMACEUTICALS 1000 N. 10th St. P.O. Box 1000 Pittsburgh, PA 15224 |
|--|---|

DEADNER



RELEASE





MAG 5 PT JAR LABEL AND BOX

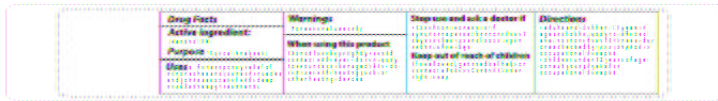
TOP

4oz

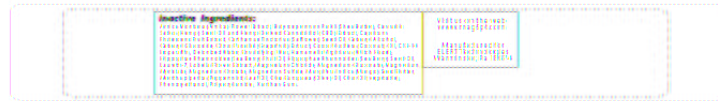


7 inches

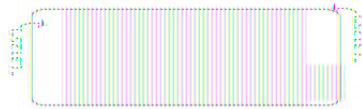
INSIDE TOP



BASE



DEADNER



RELEASE



Science and quality ingredients formulated to work synergistically to provide superior pain relief to joints, muscles and tendons.

Used & Sold by Physical & Occupational Therapists Exclusively!

Manufactured for ELERT Technologies, Warrington, Pa. 18974.



MAG 5 PT Recovery Cream

Menthol, Magnesium 5, CBD, Hemp Seed, Tibetan SeaBerry Oils & Arnica

4oz (113.02g)

Effectively used with deep muscle and soft tissue therapy treatments.



Delivers exceptional pain relief for leg cramps, muscle cramps, arthritis, neck and back pain, strains and sprains.



0 20266 18508 9



Drug Facts: Active ingredient: Menthol, Magnesium 5, CBD, Hemp Seed, Tibetan SeaBerry Oils & Arnica. Purpose: To relieve minor aches and pains. Directions: Apply to the affected area...

MAG 5 PT WARMING FORMULA

menthol cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76348-511 |
| 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) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| OLIVE OIL (UNII: 6UYK2W1W1E) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| WITCH HAZEL (UNII: 101I4J0U34) | |
| SHEA BUTTER (UNII: K49155WL9Y) | |
| LAURETH-7 (UNII: Z95S6G8201) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741) | |
| C13-14 ISOPARAFFIN (UNII: E4F12ROE70) | |
| WHITE WAX (UNII: 7G1J5DA97F) | |
| ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ) | |
| LOBELIA INFLATA LEAF (UNII: 7QFT17RLRG) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| COCONUT OIL (UNII: Q9L0O73W7L) | |
| MAGNESIUM MYRISTATE (UNII: Z1917F0578) | |
| TABASCO PEPPER (UNII: J1M3NA843L) | |
| MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2) | |
| NIACINAMIDE (UNII: 25X51I8RD4) | |
| CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S) | |
| CORN OIL (UNII: 8470G57WFM) | |
| MAGNESIUM OROTATE (UNII: GI96W46M5A) | |
| CANNABIDIOL (UNII: 19GBJ60SN5) | |
| MAGNESIUM GLUCONATE (UNII: T42NAD2KHC) | |
| HIPPOPHAE RHAMNOIDES FRUIT OIL (UNII: TA4JCF9S1J) | |
| CETEARYL GLUCOSIDE (UNII: 09FUA47KNA) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB) | |
| POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I) | |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:76348-511-05 | 1 in 1 BOX | 03/19/2019 | |
| 1 | NDC:76348-511-04 | 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 | 03/19/2019 | |

Labeler - RENU LABORATORIES, INC. (945739449)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| RENU LABORATORIES, INC. | | 945739449 | manufacture(76348-511) |

Revised: 2/2023

RENU LABORATORIES, INC.