

MUSCLE ICE- phytolacca decandra, symphytum officinale, bellis perennis, ledum palustre, ruta graveolens, magnesia phosphorica, silicea gel
Peaceful Mountain

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

DRUG FACTS:

ACTIVE INGREDIENTS:

Phytolacca Decandra 1X, Symphytum Officinale 3X, Bellis Perennis 6X, Ledum Palustre 6X, Ruta Graveolens 6X, Magnesia Phosphorica 9X, Silicea 9X.

INDICATIONS:

For the temporary relief of minor aches and pains of muscles and joints.**

**These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

WARNINGS:

For external use only. Avoid contact with eyes. If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again with a few days, discontinue use of this product and consult a doctor.

Do not apply to wounds or damaged skin.

Do not bandage tightly.

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

KEEP OUT OF REACH OF CHILDREN:

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.

Children under 2 years of age: Consult a doctor.

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INACTIVE INGREDIENTS:

Aloe Vera, Camphor Essential Oil, Carbomer (Ultrez 21), Edetate Disodium (EDTA), Ginger Essential Oil, Lavender Essential Oil, PEG-33, PEG-8 Dimethicone, PEG-14, Phenoxyethanol, Caprylyl Glycol, Sorbic Acid, Potassium Sorbate, Purified Water, Sodium Hydroxide (Solution), St. John's Wort Essential Oil, Vitamin E Oil, Menthol.

QUESTIONS:

Dist. by Peaceful Mountain, Inc.

Woodbine, IA 51579

888-303-3388

www.peacefulmountain.com

PACKAGE DISPLAY LABEL:

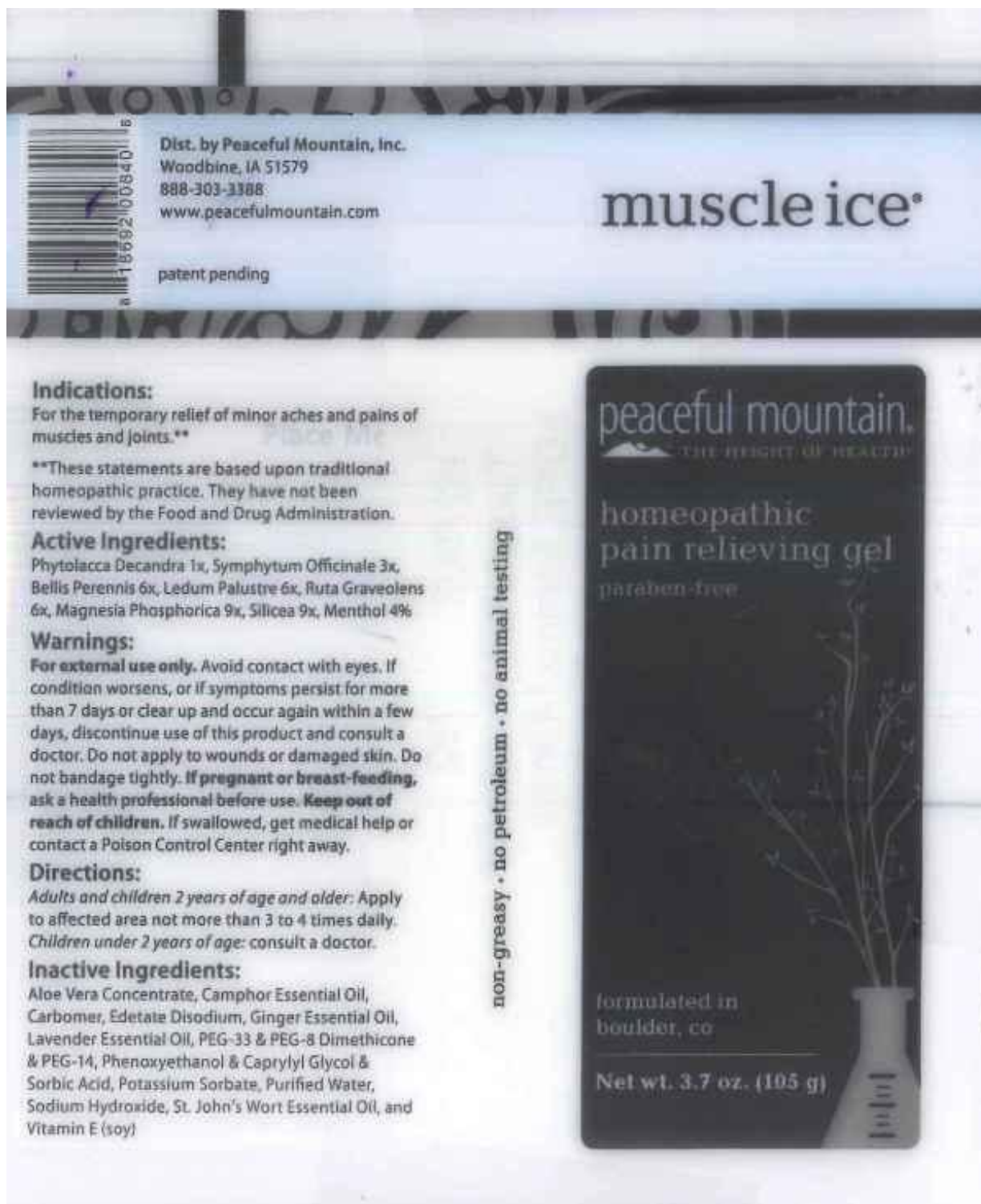
muscle ice

peaceful mountain

homeopathic

pain relieving gel

Net wt. 3.7 oz. (105 g)



MUSCLE ICE

phytolacca decandra, symphytum officinale, bellis perennis, ledum palustre, ruta graveolens, magnesia phosphorica, silicea gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:43846-0022 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | | |
|--|--|----------------------|----------------------|--------------------|
| Ingredient Name | Basis of Strength | Strength | | |
| PHYTOLACCA AMERICANA ROOT (UNII: 11E6VI8VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6VI8VEG) | PHYTOLACCA AMERICANA ROOT | 1 [hp_X] in 1 g | | |
| COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ) | COMFREY ROOT | 3 [hp_X] in 1 g | | |
| BELLIS PERENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY) | BELLIS PERENNIS | 6 [hp_X] in 1 g | | |
| LEDUM PALUSTRE TWIG (UNII: 877L01IZ0P) (LEDUM PALUSTRE TWIG - UNII:877L01IZ0P) | LEDUM PALUSTRE TWIG | 6 [hp_X] in 1 g | | |
| RUTA GRAVEOLENS FLOWERING TOP (UNII: N94C2U587S) (RUTA GRAVEOLENS FLOWERING TOP - UNII:N94C2U587S) | RUTA GRAVEOLENS FLOWERING TOP | 6 [hp_X] in 1 g | | |
| MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE (UNII: HF539G9L3Q) (MAGNESIUM CATION - UNII:T6V3LHY838) | MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE | 9 [hp_X] in 1 g | | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (COLLOIDAL SILICON DIOXIDE - UNII:ETJ7Z6XBU4) | SILICON DIOXIDE | 9 [hp_X] in 1 g | | |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| ALOE (UNII: V5VD430YW9) | | | | |
| CAMPHOR OIL (UNII: 75IZZ8Y727) | | | | |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | | | | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | | | | |
| GINGER OIL (UNII: SAS9Z1SVUK) | | | | |
| LAVENDER OIL (UNII: ZBP1YXW0H8) | | | | |
| POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A) | | | | |
| PEG-8 DIMETHICONE (UNII: GIA7T764OD) | | | | |
| POLYETHYLENE GLYCOL 700 (UNII: 762678AC5R) | | | | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | | | | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | | | | |
| SORBIC ACID (UNII: X045WJ989B) | | | | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| HYPERICUM OIL (UNII: OZU2FC70HY) | | | | |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) | | | | |
| MENTHOL (UNII: L7T10EIP3A) | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:43846-0022-1 | 105 g in 1 TUBE | | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| unapproved homeopathic | | 09/25/2013 | | |

Labeler - Peaceful Mountain (078430707)

Registrant - Apotheca Company (844330915)

| Establishment | | | |
|------------------|---------|-----------|--|
| Name | Address | ID/FEI | Business Operations |
| Apotheca Company | | 844330915 | manufacture(43846-0022) , api manufacture(43846-0022) , label(43846-0022) , pack(43846-0022) |