

MMA ELITE PAIN RELIEF - menthol, camphor gel
MMA Pain Relief Gel, LLC

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.

DRUG FACTS

| Active Ingredients | Purpose |
|--------------------|--------------------|
| Camphor (5%) | External Analgesic |
| Menthol (5%) | External Analgesic |

Uses:

temporary relief of minor aches and pains of muscles and joints due to:

- * simple backache
- * arthritis
- * sprains
- * strains
- * bruises

Warnings:

- * for external use only
- * do not apply to open wounds or damaged skin
- * do not bandage tightly
- * avoid contact with eyes
- * Keep out of reach of children. if swallowed, get medical help or contact a Poison Control Center immediately
- * if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a physician
- * Pregnancy-breast feeding warning: if pregnant or breast feeding, ask a health professional before use

Inactive Ingredients:

distilled water, hamamelis virginiana (witch hazel extract), isopropyl alcohol, arnica Montana, oleyl alcohol and zanthoxylum alatum (szechuan pepper), Bio-saccharide Gum -1, glycerin, ammonium acryloyldimethyltaurate/VP copolymer, beta cyclodextrin, menthol, potassium hydroxide, mannitol, cellulose chromium, hydroxide green, tocopheryl

acetate (vitamin E), hydroxypropyl methycellulose

Directions:

For best results, apply generously to affected and surrounding areas. Use 1 layer for minor pain, 2 for medium and 3 layers for severe symptoms. Rub in well. Allow to dry between layers (usually just 2-3 minutes). Repeat process up to 4 times daily. For adults and children 2 years and older. For children under 2 years of age, consult a doctor.

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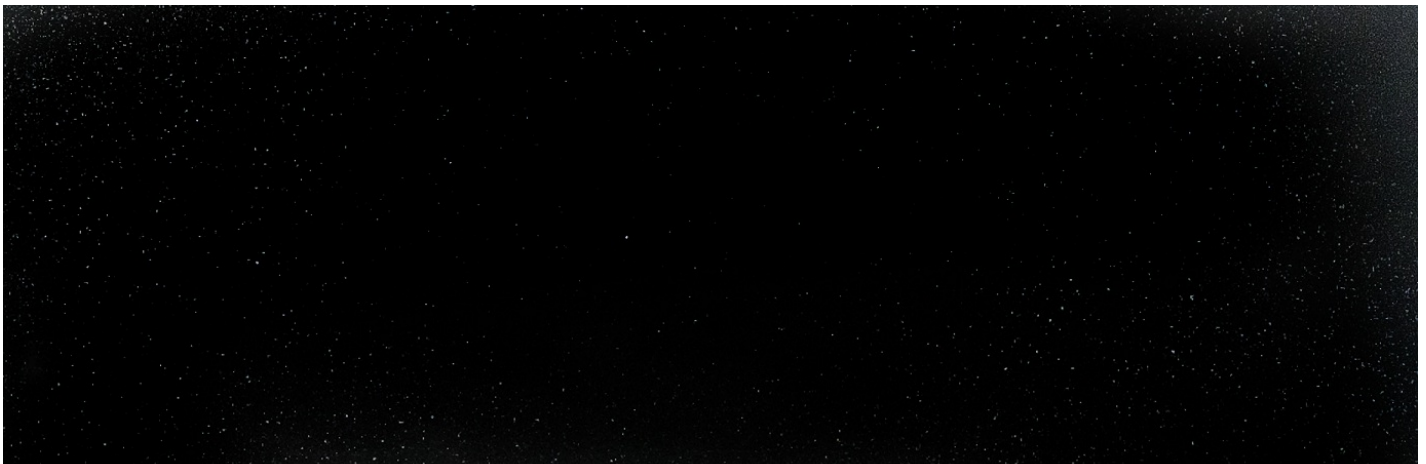
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An image/jpeg of the container label is included in this section.

ID: MM1





MMA ELITE PAIN RELIEF

menthol, camphor gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:24462-200

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------|
| menthol (UNII: L7T10EIP3A) (menthol - UNII:L7T10EIP3A) | menthol | 5 g in 100 g |
| CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941) | CAMPHOR (NATURAL) | 5 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------------|----------|
| arnica montana (UNII: O80TY208ZW) | |
| water (UNII: 059QF0K00R) | |
| Witch hazel (UNII: 101I4J0U34) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:24462-200-04 | 18 14 g in 1 JUG | | |
| 2 | NDC:24462-200-03 | 177 g in 1 TUBE | | |
| 3 | NDC:24462-200-01 | 2 g in 1 PACKET | | |
| 4 | NDC:24462-200-02 | 88 g in 1 TUBE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 11/10/2011 | |

Labeler - MMA Pain Relief Gel, LLC (009985562)

Registrant - MMA Pain Relief Gel, LLC (009985562)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| Northwest Cosmetic Labs | | 929572014 | manufacture |

Revised: 11/2011

MMA Pain Relief Gel, LLC