

NO PAIN MORE GAIN- menthol aerosol, spray

Vema Industrie-verpackung GmbH & Co. Kg. Kontrakt - Abfullung Und -verpackung

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.

Active Ingredient Menthol (0.05%)

Purpose Topical Analgesic

Use

For temporary relief of muscles and joint pain associated with arthritis, backaches, strains, sports injuries, muscle stiffness

Warnings

• For external use only • Avoid contact with the eyes and mucous membranes • Do not use on irritated skin • Do not wrap, bandage, or use a heating pad on the treated area • Do not use on open wounds or broken skin.

Stop use and ask a doctor if

• Condition worsens • skin irritation occurs • Symptoms persist for more than 7 days or clear up and occur again within a few days

Directions

Shake well. Spray onto the affected area, wait 60 seconds, until crackling effect fades. Massage in gently. Wash your hands well after using. May be used 4 to 6 times a day. Do not use in children under 12 years of age.

Other information

Contents under pressure. Do not expose to sunlight or keep where temperatures exceed 120°F. Do not spray into flames or hot surfaces. Keep away from sources of ignition. Do not puncture or incinerate container. When using this product, keep away from face and mouth to avoid breathing in.

Inactive Ingredients

Alcohol denat., Benzyl Benzoate, Butane, Citral, Citronellol, Geraniol, Glycerin, Hydroxycitronellal, Limonene, Linalool, Menthyl Lactate, Parfum, PPG-6-Decyltetradeceth-30, Propane, Sodium Polyacrylate, Water, Xanthan Gum

100% Vegan

No Pain More Gain

Ice Spray

Moisturizing Pain Relief

NPMG is • 100% vegan • Gluten-free • Free of paraben, paraffin and silicone oil • Made from spring water • Not tested on animals

For local inflammatory and noninflammatory pain. No Pain More Gain (NPMG) provides temporary but long lasting pain relief and moisturizes the skin. The innovative crackling spray contains tiny bubbles. On contact with the skin they burst and release their unique pain relieving properties. NPMG Ice Spray is cold at first, then warm. It can be used selectively, but also on large areas. The natural alternative with the advanced German formula starts to work on contact. NPMG penetrates deeply, absorbs quickly and has a fresh and pleasant scent.

Lugus Group LLC, Buffalo, WY 82834, USA

NET WT 5.07 fl oz (150 ml)

Keep out of reach of children.

NO PAIN MORE GAIN

ICE SPRAY

Moisturizing Pain Relief

100% VEGAN

| Drug Facts | | Drug Facts (continued) |
|--|-------------------------------------|--|
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| Use For temporary relief of muscles and joint pain associated with arthritis, backaches, strains, sports injuries, muscle stiffness. | | Other information Contents under pressure. Do not expose to sunlight or keep where temperatures exceed 120°F. Do not spray into flames or hot surfaces. Keep away from sources of ignition. Do not puncture or incinerate container. When using this product, keep away from face and mouth to avoid breathing in. |
| Warnings • For external use only • Avoid contact with the eyes and mucous membranes • Do not use on irritated skin • Do not wrap, bandage, or use a heating pad on the treated area • Do not use on open wounds or broken skin | | |
| Stop use and ask a doctor if • Condition worsens • Skin irritation occurs • Symptoms persist for more than 7 days or clear up and occur again within a few days. | | Inactive Ingredients: Alcohol denat., Aqua, Benzyl Benzoate, Butane, Citral, Citronellol, Geraniol, Glycerin, Hydroxycitronellal, Limonene, Linalool, Menthyl Lactate, Perfume, PPG-6-Decyltetradeceth-30, Propane, Sodium Polyacrylate, Xanthan Gum |
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LUGUS GROUP LLC
Buffalo, WY 82834, USA



NET WT. 5.07 fl oz (150 ml)

NO PAIN MORE GAIN

menthol aerosol, spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71637-003 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 5 mg in 100 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| LINALOOL, (+)- (UNII: F4VNO44C09) | |
| HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR) | |
| LIMONENE, (+)- (UNII: GFD7C86Q1W) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J) | |
| BENZYL BENZOATE (UNII: N863NB338G) | |
| GERANIOL (UNII: L837108USY) | |
| WATER (UNII: 059QF0KO0R) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| PROPANE (UNII: T75W9911L6) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I) | |
| CITRAL (UNII: T7EU0O9VPP) | |
| .BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K) | |
| 2-BROMOBUTANE, (S)- (UNII: 2AL1MZU0XA) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:71637-003-01 | 150 mg in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 08/16/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 03/01/2017 | |

Labeler - Vema Industrie-verpackung Gmbh & Co. Kg. Kontrakt - Abfullung Und -verpackung (316193515)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|------------------------|
| Vema Industrie-verpackung Gmbh & Co. Kg. Kontrakt - Abfullung Und -verpackung | | 316193515 | manufacture(71637-003) |

Revised: 12/2018

Vema Industrie-verpackung Gmbh & Co. Kg. Kontrakt - Abfullung Und -verpackung