

## **NO PAIN MORE GAIN- menthol aerosol, spray**

**Lugus Group 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.*

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**Active Ingredient** Menthol (0.05%)

**Purpose** Topical Analgesic

### **Use**

For temporary relief of muscle and joint pain associated with arthritis, backaches, bruises, 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, 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.

NPMG Ice Spray is a product of

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)
<b>Active Ingredient</b> Menthol (0.05%)	<b>Purpose</b> Topical Analgesic	<b>Directions</b> 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.
<b>Use</b> For temporary relief of muscle and joint pain associated with arthritis, backaches, bruises, strains, sports injuries, muscle stiffness.		<b>Other information</b> 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.
<b>Warnings</b> • 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		<b>Inactive Ingredients</b> Alcohol, Benzyl Benzoate, Butane, Citral, Citronellol, Geraniol, Glycerin, Hydroxycitronellal, Limonene, Linalool, Menthyl Lactate, Parfum, PPG-6-Decyltetradeceth-30, Propane, Sodium Polyacrylate, Water, Xanthan Gum
<b>Stop use and ask a doctor if</b> • Condition worsens • Skin irritation occurs • Symptoms persist for more than 7 days or clear up and occur again within a few days		
<b>Keep out of reach of children</b>		

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NPMG Ice Spray is a product of  
**LUGUS GROUP LLC** Buffalo, WY 82834, USA  
NET WT. 5.07 fl oz (150 ml)



## NO PAIN MORE GAIN

menthol aerosol, spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69161-005
<b>Route of Administration</b>	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 (250000 MW) (UNII: 05H15JN12J)	
BENZYL BENZOATE (UNII: N863NB338G)	
GERANIOL (UNII: L837108USY)	
WATER (UNII: 059QF0K00R)	
ALCOHOL (UNII: 3K9958V90M)	
PROPANE (UNII: T75W991L6)	
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:69161-005-01	150 mg in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/01/2017	

## Marketing Information

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

**Labeler** - Lugus Group LLC (079463507)

**Registrant** - Lugus Group LLC (079463507)

## Establishment

Name	Address	ID/FEI	Business Operations
Lugus Group LLC		079463507	label(69161-005)