

NO PAIN MORE GAIN- menthol 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.

Active Ingredient

Menthol (0.1%)

Purpose

Topical Analgesic

Use

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

Keep out of reach of children

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, Bambusa Vulgaris Shoot Extract, Benzyl Benzoate, Citral, Citronellol, Geraniol, Glycerin, Hordeum Vulgare Leaf Extract, Hydroxycitronellal, Limonene, Linalool, Parfum, Propylene Glycol, Sodium Polyacrylate, Sorbitol, Vanillyl Butyl Ether, Water, Xanthan Gum

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.

100% Vegan

No Pain More Gain

Hot 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 noninflammatory pain. No Pain More Gain (NPMG) Hot Spray provides instant pain relief and moisturizes the skin. The natural alternative with the advanced German formula starts to work on contact and relieves pain for hours. NPMG penetrates deeply, absorbs quickly and has a fresh and pleasant scent.

NPMG Hot Spray is a product of

Lugus Group LLC, Buffalo, WY 82834, USA

NET WT 3.4 fl oz (100 ml)

Directions

Spray a small amount directly onto the affected area up to four times a day. Do not use in children under 12 years of age. Wash your hands well after using.

NO PAIN MORE GAIN

HOT SPRAY

Moisturizing Pain Relief

100% VEGAN

Drug Facts		Drug Facts (continued)
Active Ingredient Menthol (0.1%)	Purpose Topical Analgesic	Directions Spray a small amount directly onto the affected area up to four times a day. Start with two spray pumps per area. A hot sensation occurs when the spray starts working. If no heat sensation occurs within 6 hours add another spray pump per area to the next application. Massage in gently. Wash your hands well after using. Do not use in children under 12 years of age
Use For temporary relief of muscle and joint pain associated with arthritis, backaches, strains, sports injuries, muscle stiffness.		
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NO PAIN MORE GAIN

menthol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69161-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.1 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
BENZYL BENZOATE (UNII: N863NB338G)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
VANILLYL BUTYL ETHER (UNII: S2ULN37C9R)	

LINALOOL, (-)- (UNII: 3U21E3V8I2)
ALCOHOL (UNII: 3K9958V90M)
GERANIOL (UNII: L837108USY)
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)
HORDEUM VULGARE TOP (UNII: 86507VZR9K)
SODIUM POLYACRYLATE (250000 MW) (UNII: 05115JN12J)
BAMBUSA VULGARIS STEM (UNII: SMR633LHTC)
XANTHAN GUM (UNII: TTV12P4NEE)
SORBITOL (UNII: 506T60A25R)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
WATER (UNII: 059QF0KO0R)
CITRAL (UNII: T7EU0O9VPP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69161-003-01	100 mg in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/01/2016	

Labeler - LUGUS GROUP LLC (079463507)

Registrant - LUGUS GROUP LLC (079463507)

Establishment

Name	Address	ID/FEI	Business Operations
LUGUS GROUP LLC		079463507	label(69161-003)