NO PAIN MORE GAIN- menthol cream 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

 $\Box Use$

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

Keep out of reach of children.

Directions

Shake Well. Adults and children of 2 years and older apply to the affected areas up to 6 times a day. Massage in gently.

□ Warnings

• For external use only • Avoid contact with the eyes and mucous membranes • Do not use with a heating pad • Do not use on open wounds or broken skin

100% Vegan

No Pain More Gain Cream

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 pain treatment and as preventive measure. Best for use on large areas. No Pain More Gain (NPMG) provides temporary but long lasting pain relief and moisturizes the skin. 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 Cream is a product

Lugus Group LLC, Buffalo, WY 82834

NET WT 5.07 fl oz (150 ml)

Inactive Ingredients

Alcohol, Ascorbic Acid, Ascorbyl Palmitate, Benzoic Acid, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Citral, Citric Acid, Citrus Medica Limonum (Lemon) Peel Oil, Dehydroacetic Acid, Dicaprylyl Carbonate, Ethylhexylglycerin, Ethylhexyl Stearate, Galactoarabinan, Glycerin, Gold, Limonene, Panthenol, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, Phenoxyethanol, Platinum Powder, PPG-3 Benzyl Ether Myristate, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Silica, Sodium Hydroxide, Sodium Stearoyl Glutamate, Squalene, Tetrasodium Glutamate Diacetate, Tocopherol, Water, Xanthan gum.

Stop use and ask a doctor if

• Condition worsens • Skin irritation occurs • Symptoms persist for more than 7 days or clear up and



CREAM

Moisturizing
Pain Relief

100% VEGAN

Drug Facts

Active Ingredient Purpose Menthol (0.1%) Purpose Topical Analgesic

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Warnings

• For external use only • Avoid contact with the eyes and mucous membranes • Do not use with a heating pad • 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
- Keep out of reach of children

Drug Facts (continued)

Directions

• Shake well • Adults and children of 2 years and older apply to the affected areas up to 6 times a day • Massage in gently.

Inactive Ingredients

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NO PAIN MORE GAIN

menthol cream

Product Information

Route of Administration

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69161-001
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Active Ingredient/Active Mojety

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	Ingredient Name	Basis of Strength	Strength
	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg in 100 mg

Inactive Ingredients Ingredient Name Strength PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDRO XYPHENYL) PROPIONATE) (UNII:

255PIF62MS) **GOLD** (UNII: 79 Y1949 PYO)

TOPICAL

WATER (UNII: 059QF0KO0R)

DICAPRYLYL CARBONATE (UNII: 609 A3V1SUA)

ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)

GLYCERIN (UNII: PDC6A3C0OX)

CETOSTEARYL ALCOHOL (UNII: 2DMT128 M1S)	
ALMOND OIL (UNII: 66 YXD4DKO9)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
PPG-3 BENZYL ETHER MYRISTATE (UNII: 8075L58MKO)	
PANTHENOL (UNII: WV9CM0O67Z)	
SQUALANE (UNII: GW89575KF9)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GALACTO ARABINAN (UNII: SL4SX1O487)	
LEMON OIL (UNII: 19 GRO 824LL)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)	
LIMO NENE, (+)- (UNII: GFD7C86Q1W)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TETRASO DIUM GLUTAMATE DIACETATE (UNII: 5EHL50 I4MY)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	
PLATINUM (UNII: 49 DFR0 88 MY)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALCOHOL (UNII: 3K9958V90M)	
DEHYDRO ACETIC ACID (UNII: 2KAG279 R6 R)	
CITRAL (UNII: T7EU0O9VPP)	

l	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:69161-001-01	100 mg in 1 PACKAGE; Type 0: Not a Combination Product	08/29/2014	05/02/2017	
	2 NDC:69161-001-02	150 mg in 1 PACKAGE; Type 0: Not a Combination Product	05/02/2016		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	08/29/2014		

Labeler - Lugus Group LLC (079463507)

Registrant - Lugus Group LLC (079463507)

Establishment					
Name	Address	ID/FEI	Business Operations		
Lugus Group LLC		079463507	label(69161-001)		

Revised: 12/2019 Lugus Group LLC