SIGFORM HERBAL MUSCLE- menthol and camphor gel Signature Formulations 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.

Sigform Science & Health Herbal Muscle Gel

Active ingredient

Menthol USP 6% Camphor 2%

Purpose

Pain Relief

Other ingredients

Purified Signature Water™, Methylsufonylmethane, Lubragel Np, Menthol crystals, Eucaliptus oil, Camphor powder, Peppermint oil, Clove Bud oil, Phenoxyethanol, Carbopol ultrez 10, Sweet Birch oil, Sodium bicarbonate, Potassium Sorbate.

Uses

For the temporary relief of minor aches and pains at muscles and joints associated with sore muscles, strains, joint discomfort & arthritis.

Warnings

Discontinue use if irritation or red skin develops, and consult a physician. Application is intended for external cosmetic use only. Consult a health care professional before using this or any product during pregnancy or while breastfeeding. Do not use around the eye area. Do not use if tamper-evident seal is broken or missing. Store in cool dry place.

These statements have not been evaluated by the food and drug administration. This product is not intended to treat, cure or prevent any disease.

Keep Out of Reach of Children

Directions

Adults and children over 12 years. Massage into neck and shoulders to help relieve tension and stress. Rub into temples to help with headaches, and chest to relieve cold and flu. Apply prior to a workout or sports activity.

Manufactured in a FDA registered facility by

Signature Formulations LLC. Phoenix, AZ

Package/Label Principal Display Panel

Sigform

SCIENCE & HEALTH

NATURALLY PRESERVED PARABEN FREE

HERBAL MUSCLE GEL

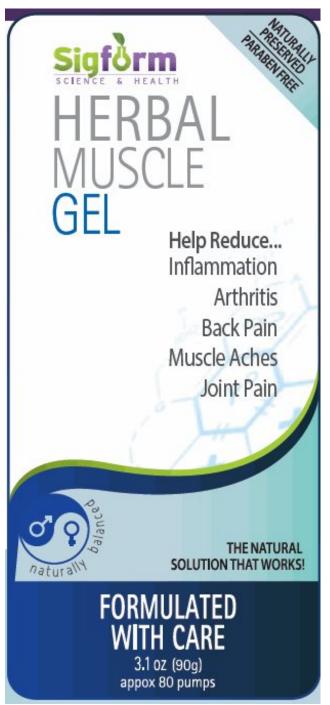
Help Reduce...
Inflammation
Arthritis
Back Pain
Muscle Aches
Joint Pain

naturally balanced

THE NATURAL SOLUTION THAT WORKS!

FORMULATED WITH CARE

3.1 oz (90g) approx 80 pumps



Carton Label

SIGFORM HERBAL MUSCLE

menthol and camphor gel

Product Inform	ation	
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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:69257-212

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	in 100 mL
	CAMPHOR (SYNTHETIC)	2 g in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)			
EUCALYPTUS OIL (UNII: 2R04ONI662)			
PEPPERMINT OIL (UNII: AV092KU4JH)			
CLOVE OIL (UNII: 578389 D6 D0)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)			
METHYL SALICYLATE (UNII: LAV5U5022Y)			
SODIUM BICARBONATE (UNII: 8MDF5V39QO)			
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69257-212- 22	90 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	0 1/15/20 15		

Labeler - Signature Formulations LLC (079126258)

Registrant - Signature Formulations LLC (079126258)

Establishment				
Name	Address	ID/FEI	Business Operations	
Signature Formulations LLC		079126258	MANUFACTURE(69257-212)	

Revised: 4/2015 Signature Formulations LLC