# SIGFORM HERBAL MUSCLE- menthol and camphor lotion 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.

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### Sigform Science & Health Herbal Muscle Lotion

#### **Active ingredient**

Menthol USP 6% Camphor 2%

#### **Purpose**

Pain Relief

#### Other ingredients

Purified Signature Water<sup>TM</sup>, Menthol Crystals, Methylsufonylmethane, Vegetable Glycerin, Caprylic Triglyceride, Stearic Acid, Coconut oil, Olive oil, Eucaliptus Oil, Peppermint Oil, Sweet Birch Oil, Clove Bud Oil, Aloe Vera Gel, Potassium Sorbate, Allantoin, Herbal active, Carbomer.

#### 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 LOTION

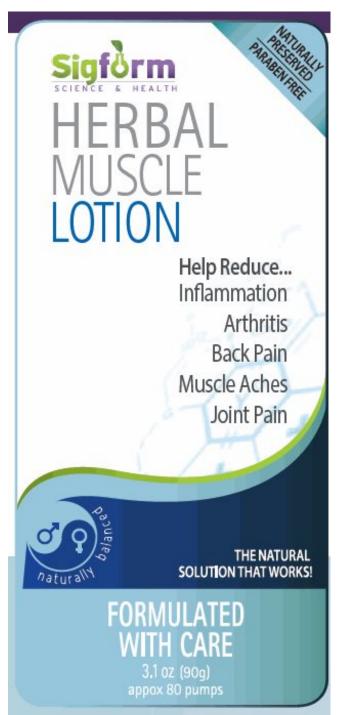
Help Reduce...
Inflammation
Arthritis
Back Pain
Muscle Aches
Joint Pain

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 lotion

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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:69257-211

Route of Administration TOPICAL

**Active Ingredient/Active Moiety** 

Ingredient Name Basis of Strength Strength

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	6 g in 100 mL
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	2 g in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)			
GLYCERIN (UNII: PDC6A3C0OX)			
TRICAPRYLIN (UNII: 6P92858988)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
COCONUT OIL (UNII: Q9L0O73W7L)			
OLIVE OIL (UNII: 6UYK2W1W1E)			
EUCALYPTUS OIL (UNII: 2R04ONI662)			
PEPPERMINT OIL (UNII: AV092KU4JH)			
METHYL SALICYLATE (UNII: LAV5U5022Y)			
CLOVE OIL (UNII: 578389 D6 D0)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)			
ALLANTO IN (UNII: 344S277G0Z)			

]	Packaging			
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69257-211- 21	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(69257-211)	