

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.

Sigform Science & Health Herbal Muscle Lotion

Active ingredient

Menthol USP 6%
Camphor 2%

Purpose

Pain Relief

Other ingredients

Purified Signature Water™, Menthol Crystals, Methylsulfonylmethane, 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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69 257-211
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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: 578389D6D0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ALLANTOIN (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	01/15/2015	

Labeler - Signature Formulations LLC (079126258)

Registrant - Signature Formulations LLC (079126258)

Establishment

Name	Address	ID/FEI	Business Operations
Signature Formulations LLC		079126258	MANUFACTURE(69257-211)