

MUSCLE MIST- menthol, camphor solution
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.

Muscle Mist

Active ingredient

Menthol USP 6%
Camphor 2%

Purpose

Pain Relief

Other ingredients

The Isopropyl Alcohol, Camphor Powder, Eucalyptus, Globulus Leaf Oil, Sweet Birch Oil, Peppermint Oil, Clove Bud Oil

Uses

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

Warnings

For external use only. Avoid contact with eyes. Do not apply to wounds or damaged skin. If pregnant or breast feeding ask a health care professional before use. Keep out of reach of children. If swallowed get medical help or contact a poison control center. Flammable: Keep away from fire or flame.

Keep Out of Reach of Children

Directions

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

Manufactured for:

Holistic Earth Remedies
Phoenix, Arizona 602.300.3691
holisticearthremedies.com

Package/Label Principal Display Panel

HERBAL
MUSCLE MIST

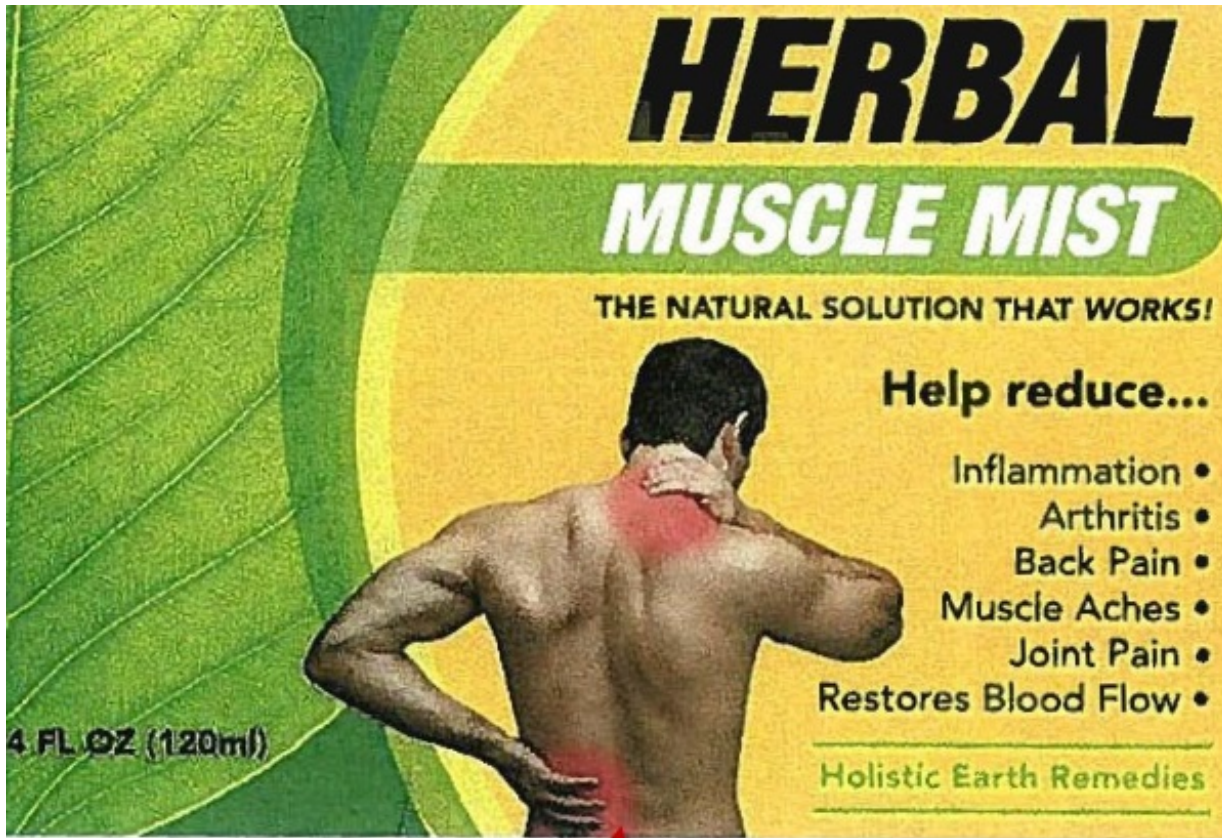
THE NATURAL SOLUTION THAT WORKS!

Help reduce...

- Inflammation •
- Arthritis •
- Back Pain •
- Muscle Aches •
- Joint Pain •
- Restores Blood Flow •

Holistic Earth Remedies

4 FL OZ (120ml)



Carton Label

MUSCLE MIST

menthol, camphor solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69257-110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: J7T1QEP2A) (MENTHOL (UNII: J7T1QEP2A))	MENTHOL	6 g

MENTHOL (UNII: L710E1F3A) (MENTHOL - UNII: L710E1F3A)	MENTHOL	in 100 mL
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
CLOVE OIL (UNII: 578389D6D0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69257-110-10	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part348	10/20/2014	

Labeler - Signature Formulations LLC (079126258)

Registrant - Signature Formulations LLC (079126258)

Establishment

Name	Address	ID/FEI	Business Operations
Signature Formulations LLC		079126258	MANUFACTURE(69257-110)

Revised: 11/2014

Signature Formulations LLC