

**COLD LEAF NUTRITION MUSCLE AND JOINT PAIN RELIEF- menthol gel
NATURAL ESSENTIALS, INC.**

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.

Cold Leaf Nutrition Inc.

DRUG FACTS

ACTIVE INGREDIENTS

NATURAL Menthol USP 3.7%

PURPOSE:

TOPICAL ANALGESIC

***USES:**

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.

WARNINGS:

Use only as directed.

- For external use only
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a physician.
- Avoid contact with eyes or mucous membranes
- **Pregnancy - Breast Feeding Warning:**
- **If pregnant or breast feeding, ask a physician before use.**
- Do not use with other topical products
- Do not use with heating devices
- Do not use on open wounds, damaged or irritated skin
- Keep away from excessive heat or open flame.
- **KEEP THIS AND ALL MEDICINE OUT OF REACH OF CHILDREN.**
- **Accidental ingestion:** Seek professional help and contact Poison Control immediately.

DIRECTIONS:

Adults and children 12 years and older

- Apply and gently massage painful joints and/or muscles.
- Repeat as needed no more than 4 times a day.
- Wash hands after each use with cold water

OTHER:

Store in cool dry area - close cap tight

INACTIVE INGREDIENTS:

†Aloe Barbadensis Leaf Extract, †Arnica Montana Extract, Camphor, Carbomer, Ethylhexylglycerin, †Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Phenoxyethanol, Tea Tree Oil, Tocopheryl Acetate (Vitamin E Acetate), Water.

†This symbol before the ingredient indicates certified organic:

Principal Display Panel - Cold Leaf Nutrition Container Label

MUSCLE & JOINT PAIN RELIEF*

Leaf Cold Nutrition

ALOE AND ARNICA, VITAMIN E AND TEA TREE OIL
GREASELESS • VANISHING SCENT • ROLL-ON FORMULA

NO PARABENS • NO SYNTHETIC FRAGRANCE • NO SULFATES
NO PARAFFINS • NO DEA • NO PETROLATUM • NO MINERAL OIL
• NO ANIMAL TESTING

89 mL (3 fl oz)

- SHAKE WELL -

DRUG FACTS	
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NO NSAID'S, IBUPROFEN, ASPIRIN OR SALICYLATE

Cold Leaf Nutrition Inc.

Muscle & Joint Pain Relief
can be used for temporary relief of minor aches and pains of muscles associated with simple backache, strains, bruises and sprains



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 **MADE IN THE U.S.A.**  **RECYCLABLE** **89 mL (3 fl oz)**

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COLD LEAF NUTRITION MUSCLE AND JOINT PAIN RELIEF

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-114
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	37 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA (UNII: O80TY208ZW)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TEA TREE OIL (UNII: VIF565UC2G)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-114-13	89 mL in 1 CONTAINER; Type 0: Not a Combination Product	09/27/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/27/2018	

Labeler - NATURAL ESSENTIALS, INC. (947484713)

Establishment

Name	Address	ID/FEI	Business Operations
NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-114)