

ICE MUSCLE RUB LEON M.C- menthol gel
Southern Sales & Service, 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.

Active Ingredients	Purpose
Menthol 2.0%	Topical Anagesic

Purpose

Topical Analgesic

Uses

temporary relief minor pains due to:

- Arthritis
- Muscle Strains
- Minor Backaches
- Sprains
- Cramps
- Bruises

Warnings

For external use only

When using this product

- Keep away from eyes and Mouthdo not bandage tightly
- Do not apply to wounds or broken skin
- Do not bandage or use with heating pad.

Keep out of reach of children

If swallowed get medical help or contact a Poison Control Center immediately.

Directions

adults and children over 12 years:

- Apply to affected area and massage until Gel is absorbed
- Repeat as necessary but no more than 4 times daily
- Children 12 years or younger:Ask your doctor

Inactive ingredients carbomer, propylene glycol, methylparaben, isopropyl alcohol, triethanolamine, FD&C Blue #1, water

Distributed by

Leon Medical Centers, Ic.

Miami, FL 33165

Question or Comments?

Call 1 800.213.9370

Stop use and ask a doctor if

- Condition worsens
- Symptoms persist for more than 7 days or clear up and occur again within a few days
- Irritation develops

Leon Medical Muscle Rub Gel

Drug Facts
Active Ingredients
Menthol 2.0%
Purpose
Topical Analgesic

Uses
Use temporarily relieves minor pains due to:
■ Arthritis ■ Strains ■ Simple Backage ■ Sprains ■ Bruises

Warnings For external use only. Avoid contact with eyes.

When using this product
■ do not bandage tightly
■ do not apply to wounds or damaged skin

Stop Use and Ask a Doctor If ■ condition worsens
■ if symptoms persist for more than 7 days or clear up and occur again within a few days*

Keep out of the Reach of Children. If swallowed get medical help or contact a Poison Control Center immediately. If pregnant or breast-feeding, ask a health professional before use.

NDC # 69822-103-08
LEON MEDICAL CENTERS
ICE
Topical Analgesic
Net Wt. 8 oz (227g)

Drug Facts (continued)
Directions
Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily.
Children under 2 years of age: consult a doctor.

Inactive Ingredients: carbomer, FD&C blue no. 1, isopropyl alcohol, methylparaben, propylene glycol, triethanolamine, purified water.

DISTRIBUTED BY:
Southern Sales Services Inc.
Pembroke Pines, FL 33332
Questions or Comments?
Call 1800.213.9370

8 919231001631 2
Lot No.:
Exp. Date:

ICE MUSCLE RUB LEON M.C

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69822-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
TROLAMINE (UNII: 9O3K93S3TK)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69822-103-08	227 g in 1 TUBE; Type 0: Not a Combination Product	01/04/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2013	

Labeler - Southern Sales & Service, Inc. (013114906)

Establishment

Name	Address	ID/FEI	Business Operations
Southern Sales & Service, Inc.		013114906	LABEL(69822-103)

Establishment

Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	MANUFACTURE(69822-103)

Revised: 1/2017

Southern Sales & Service, Inc.