

LEADER ULTRA STRENGTH MUSCLE RUB- camphor, menthol, and methyl salicylate cream

Cardinal Health, 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
Camphor 4%.....	Topical analgesic
Menthol 10%.....	Topical analgesic
Methyl salicylate 30%.....	Topical analgesic

Uses temporarily relieves the minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only

Do not use

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if you

- have a redness over the affected area

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs

Keep out of reach of children to avoid accidental ingestion.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- use only as directed
- adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

Other information

- store between 20° to 25°C (68° to 77°F)
- lot no. & exp. date: see carton or see crimp of tube

Inactive ingredients

glycerin, isopropyl myristate, lanolin, methylparaben, petrolatum, polysorbate 60, potassium cetyl phosphate, propylparaben, sorbitan monostearate, stearyl alcohol, water

DISTRIBUTED BY

CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com

1-800-200-6313

Essential to care™ since 1979

Made in Korea



LEADER ULTRA STRENGTH MUSCLE RUB			
camphor, menthol, and methyl salicylate cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0238
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	40 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	300 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0238-1	1 in 1 BOX	08/16/2017	
1		57 g in 1 TUBE; 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	08/16/2017	

Labeler - Cardinal Health, Inc. (097537435)

Revised: 8/2017

Cardinal Health, Inc.