

DEEP MUSCLE RUB- camphor ointment
LAI DEN MONTANA EMU PRODUCTS

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.

Deep Muscle Rub

Active ingredient

Camphor 4.6%

Purpose

Topical analgesic

Uses

for the temporary relief of 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

When using this product

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

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away

Directions

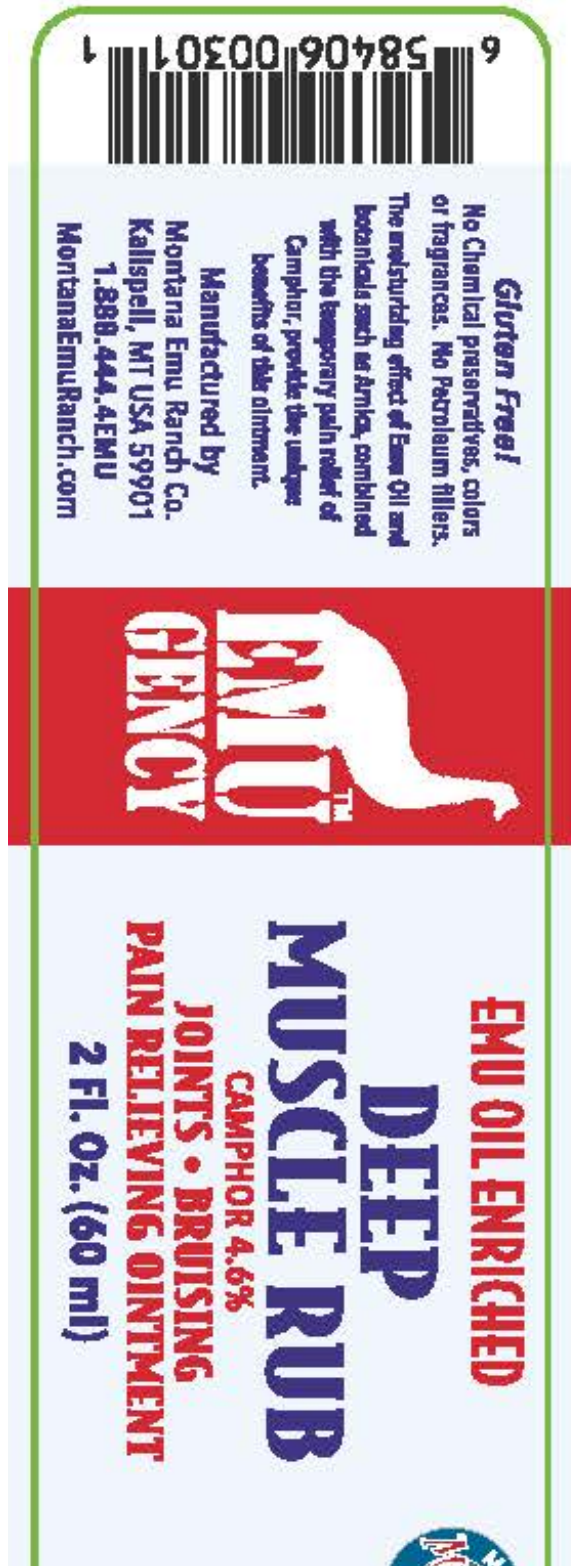
- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.
- massage into area until thoroughly absorbed
- Children under 2 years of age: consult a doctor.

Other information

- Best stored at room temperature or cooler.

Inactive ingredients

Helianthus Annuus (Sunflower) Seed Oil, Emu Oil, Beeswax, Butyrospermum Parkii (Shea) Butter, Arnica Montana Flower, Calendula Officinalis (Calendula) Flower, Melissa Officinalis (Lemon Balm) Leaf, Chamomilla Recutita (Chamomile) Flower, Tocopherol, Melaleuca Leucadendron Cajaputi (Cajeput) Oil, Lavandula Angustifolia (Lavender) Oil, Eucalyptus Globulus (Eucalyptus) Leaf Oil, Chamomilla Recutita (Chamomile) Oil, Citrus Grandis (Grapefruit) Seed Extract.





Drug Facts

Active ingredient	Purpose
Camphor 4.6%	Topical analgesic

Uses: for the temporary relief of 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

When using this product

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

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.
- message into area until thoroughly absorbed.
- Children under 2 years of age: consult a doctor.

Other information:

- Best stored at room temperature or cooler.

Inactive ingredients: Helianthus Annuus (Sunflower) Seed Oil, Emu Oil, Beeswax, Butyrospermum Paridi (Shea) Butter, Arnica Montana Flower, Calendula Officinalis (Calendula) Flower, Melissa Officinalis (Lemon Balm) Leaf, Chamomilla Recutita (Chamomile) Flower, Tocopherol, Melaleuca Leucadendron Cajaputi (Cajaput) Oil, Lavandula Angustifolia (Lavender) Oil, Eucalyptus Globulus (Eucalyptus) Leaf Oil, Chamomilla Recutita (Chamomile) Oil, Citrus Grandis (Grapefruit) Seed Extract.

DEEP MUSCLE RUB

camphor ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72895-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	2.576 g in 60 mL

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
EMU OIL (UNII: 344821WD61)	
MATRICARIA CHAMOMILLA FLOWERING TOP (UNII: 3VNC7T6Z02)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
GRAPEFRUIT SEED OIL (UNII: 598D944HOL)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SHEA BUTTER (UNII: K49155WL9Y)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CAJUPUT OIL (UNII: J3TO6BUQ37)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72895-001-04	120 mL in 1 JAR; Type 0: Not a Combination Product	02/20/2019	
2	NDC:72895-001-02	60 mL in 1 JAR; Type 0: Not a Combination Product	02/20/2019	
3	NDC:72895-001-08	240 mL in 1 JAR; Type 0: Not a Combination Product	02/20/2019	
4	NDC:72895-001-25	7 mL in 1 JAR; Type 0: Not a Combination Product	02/20/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/24/2019	

Labeler - LAIDEN MONTANA EMU PRODUCTS (960935344)

Establishment

Name	Address	ID/FEI	Business Operations
LAIDEN MONTANA EMU PRODUCTS		960935344	manufacture(72895-001)

Revised: 2/2019

LAIDEN MONTANA EMU PRODUCTS