

**HOT SPICE AND ICE- menthol, capsicum oleoresin cream
laiden 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.

Hot Spice and Ice Arthritis Pain Relieving Cream 2 oz

Active Ingredients

Active ingredients

Menthol 2.25%

Capsicum oleoresin 0.20%

Uses

Uses for the temporary relief of minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Provides:

- penetrating pain relief

Warnings

For external use only

Do not use

Do not use

- on wounds or damaged skin
- with heat

When using this product

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

Stop use and ask a doctor if

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- 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

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

Directions

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- Adults and children 12 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 12 years of age: consult a doctor.

Inactive Ingredients

Inactive ingredients Aloe Barbadensis (Aloe) Leaf Gel, Emu Oil, Vitis Vinifera (Grape) Seed Oil, Beeswax, Mixed Tocopherol, Arnica Montana Flower, Mentha Piperita (Peppermint) Leaf Oil, Gaultheria Procumbens (Wintergreen) Leaf Oil, Eucalyptus Globulus (Eucalyptus) Leaf Oil, Melaleuca Leucadendron Cajaputi (Cajeput) Oil, Capsicum Frutescens (Capsicum) Oil, Xanthan Gum

Purpose

Purpose

Topical analgesic

Principal Display Panel

Hot Spice and Ice

Arthritis Pain Relieving Cream

Drug Facts (continued)
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Gluten Free!
 No Chemical preservatives, colors or fragrances. No Petroleum fillers.
 The deep moisturizing effect of Emu Oil combined with the temporary pain relief provided by menthol and capsiicum the unique benefits of this effective analgesic rub.

Manufactured by
 Montana Emu Ranch Company
 Kalispell, MT USA 59901
 1.888.444.4EMU
 www.MontanaEmuRanch.com

**EMU OIL ENRICHED
 HOT SPICE & ICE
 ARTHRITIS
 PAIN RELIEVING CREAM**

MADE IN MONTANA USA

For simple backache strains bruises sprains

NDC 72895-002-02

Drug Facts
Active ingredients Purpose
 Topical
 Menthol 2.25%analgesic
 Capsicum Topical
 oleoresin 0.20%analgesic

▶ Peel here for drug facts

Drug Facts (continued)

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HOT SPICE & ICE

Display Panel

HOT SPICE AND ICE			
menthol, capsiicum oleoresin cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72895-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.28 g in 56.7 g
CAPSICUM OLEORESIN (UNII: UW86K581WY) (CAPSICUM OLEORESIN - UNII:UW86K581WY)	CAPSAICIN	113 mg in 56.7 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
XANTHAN GUM (UNII: TTV12P4NEE)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
MELALEUCA CAJUPUTI LEAF OIL (UNII: 5O59RMR6DU)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
TABASCO PEPPER (UNII: J1M3NA843L)	
EMU OIL (UNII: 344821WD61)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72895-002-02	56.7 g in 1 JAR; Type 0: Not a Combination Product	06/01/2019	
2	NDC:72895-002-25	7.5 g in 1 JAR; Type 0: Not a Combination Product	06/01/2019	
3	NDC:72895-002-04	113.4 g in 1 JAR; Type 0: Not a Combination Product	06/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/01/2019	

Labeler - laiden montana emu products (960935344)

Establishment

Name	Address	ID/FEI	Business Operations
laiden montana emu products		960935344	manufacture(72895-002)