THERAPEUTIC HERBAL MUSCLE CALM CAPSICUM- capsicum lotion Eco-Logics, 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.

Drug Facts

Active Ingredients

Purpose

Capsicum.025%

Topical Analgesic

Uses

Uses Temporarily relieves minor pain of muscles and joints associated with:

- arthritis
- simple back ache
- strains
- bruises

Warnings

Warnings For external use only.

When using this product

When using this product

- use only as directed
- do not bandage
- do not use with a heating pad
- avoid contact with eyes and mucous membranes
- do not apply to wounds, damaged, broken or irritated skin
- a transient burning sensation may occur upon application but generally disappears in several days
- if severe burning sensation occurs, discontinue use immediately
- do not expose the area treated with product to heat or direct sunlight

Stop use and ask a doctor if

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- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness is present
- irritation develops

If pregnant or breastfeeding

If pregnant or breastfeeding, ask a health professional before use. Keep out of reach of children.

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

Directions

Directions

adults and children over 18 years:

- apply to affected area
- massage into painful area until thoroughly absorbed
- repeat as necessary, but no more than 3 to 4 times daily
- WASH HANDS WITH SOAP AND WATER AFTER APPLYING
- children 18 years or younger: ask a doctor

Keep out of the reach of children.

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

Directions

Directions

Adults and children 2 years of age and older:

- Apply to painful muscles and joint. Gently massage thoroughly into affected area.
- Repeat as necessary but not more than 4 times daily.

Purpose

Active Ingredients Purpose

Capsicum .025%...... Topical Analgesic

Inactive Ingredients

Aqueous (Deionized Water) infusion of botanical extracts of Passiflora Incarnata, Arnica Montana, Ruscus Acluteatus, Hypericum Perforatum, Arctium Lappa, Anthemis Nobilis, *Aloe Barbadensis, Custom blend of *Helianthus annuus (Sunflower Oil),* Olea Europaea (Olive Oil), *Simmondsia Chinenesis (Jojoba Oil), *Linum Usitatissimum (Flax Seed Oil), Boswellia Serrata, Methylsulfonylmethane, Glycerin, Ceteareth-20, Cetyl Alcohol, Stearyl Alcohol, Juniperus Communis Oil, Origanum Marjorana Oil, Lavandula Officinalis Oil, Rosmarinus Officianalis Oil, Thymus Zygis Oil, Tocopherol (Vitamin E), Phenoxyethanol, Ethylhexylglycerin

yerbal muscle calm

<u>Herbal Muscle Calm</u> Therapeutic

Results - Doctor Recommended refers to Capsaicin ingredient) Arthritis Muscle & Joint Relief **Powerful Herbs for Powerful** Formula - Deep Penetrating Topical Analgesic with

extracts, boswellia, MSM, capsaicin, organic Specially formulated with natural botanical with muscular aches, pains & neuropathy aloe vera, organic omega seed oils rich in essential fatty acids, all which can help

8 fl. oz. / 236 ml

Therapeutic Herbal Muscle Calm

Arthritis Muscle and Joint Relief Formula

Active Ingredient **Drug Facts**

Capsaicin .025% . . .

Purpose Topical Analge

USeS temporarily relieves minor pain of muscles and joints associated with arthritis simple backache strains bruises

Warnings For external use only.

When using this product ■ use only as directed ■ do not bandage ■ do ruse with a heating pad ■ avoid contact with eyes and mucous membranes

a transient burning sensation may occur upon application but generally do not apply to wounds, damaged, broken or irritated skin

disappears in several days If severe burning sensation occurs, discontinue use immediately and remov

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 ■ redness is

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a

Directions
adults and children over 18 years: ■ apply to affected area ■ massage into painful area unit broughly absorbed ■ repeat as necessary, but no more than 3104 times daily ■ WASH HANDS WITH SODA AND WATER AFTER APPLYING children 18 years or younger: ask a doctor

Tocopherol (Vitamin E), Phenoxyethanol, Ethylhexylglycerir 'THIS SYMBOL BEFORE THE INGREDIENT INDICATES THAT IT IS ORGANIC

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An Eco-Friendly Company



THERAPEUTIC HERBAL MUSCLE CALM CAPSICUM capsicum lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30056-007
Route of Administration	TOPICAL		

l	Active Ingredient/Active Moiety			
ı	Ingredient Name	Basis of Strength	Strength	
ı	Capsicum (UNII: 00UK7646FG) (Capsicum - UNII:00UK7646FG)	Capsicum	.25 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Ruscus Aculeatus Root (UNII: ZW12V95I1Q)	
Hypericum Perforatum (UNII: XK4IUX8MNB)	
Arctium Lappa Root (UNII: 597E9BI3Z3)	
Passiflora Incarnata Top (UNII: CLF5YFS11O)	
Arnica Montana (UNII: O80TY208ZW)	
Chamaemelum Nobile (UNII: 7NF3GE7IWR)	
Aloe Vera Leaf (UNII: ZY8 1Z8 3H0 X)	
Sunflower Oil (UNII: 3W1JG795YI)	
Olive Oil (UNII: 6UYK2W1W1E)	
Jojoba Oil (UNII: 724GKU717M)	
Linseed Oil (UNII: 84XB4DV00W)	
Frankincense (UNII: R9 XLF1R1WM)	
Dimethyl Sulfone (UNII: 9H4PO4Z4FT)	
Glycerin (UNII: PDC6A3C0OX)	
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWUY)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Stearyl Alcohol (UNII: 2KR8914H1Y)	
Juniper (UNII: 464910T5N9)	
Sweet Marjoram Oil (UNII: ICH7BE016E)	
Lavender Oil (UNII: ZBP1YXW0H8)	
Rosemary Oil (UNII: 8LGU7VM393)	
Thyme Oil (UNII: 2UK410MY6B)	
Alpha-Tocopherol (UNII: H4N855PNZ1)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Ethylhexylglycerin (UNII: 147D247K3P)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30056-007-08	236 g in 1 BOTTLE, DISPENSING		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final part348 06/15/2010

Labeler - Eco-Logics, Inc. (047667022)

Revised: 4/2011 Eco-Logics, Inc.