

EARTHS CARE ARTHRITIS- capsaicin cream
DLC Laboratories, 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.

EARTH'S CARE™ ARTHRITIS CREAM

Drug Facts

Active ingredient

Capsaicin 0.1%

Purpose

Topical analgesic

Uses

temporarily relieves minor pain of muscles and joints associated with:

- arthritis
- simple backache
- strains
- sprains
- bruises

Warnings

For external use only

When using this product

- read leaflet inside carton before use
- use only as directed
- do not bandage tightly or cover treated area
- do not use with a heating pad or other heat sources
- avoid contact with eyes and mucous membranes
- do not apply to wounds, damaged, broken or irritated skin
- a temporary burning sensation may occur upon application but normally disappears within several days
- if a severe burning sensation occurs, stop use immediately and read important information on leaflet inside carton
- do not expose the area treated with product to heat or direct sunlight
- do not apply immediately before or after activities such as bathing, swimming, sunbathing or strenuous exercise

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 present
- irritation develops

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 Poison Control Center right away.

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 or 4 times daily
- **WASH HANDS WITH SOAP AND COLD WATER AFTER APPLYING**

Children 18 years or younger: ask a doctor

Inactive ingredients

beeswax, *Butyrospermum parkii* (shea) butter, cetearyl glucoside, cetyl alcohol, citric acid, glycerin, glyceryl stearate, heptyl undecylenate, hydrogenated castor oil, *Oryza sativa* (rice) bran extract, phenoxyethanol, potassium sorbate, *Prunus amygdalus dulcis* (sweet almond) oil, purified water, sodium stearoyl glutamate, sodium stearoyl lactylate, stearic acid, xanthan gum

Questions

1-888-602-6380

Distributed by:

Earth's Care Natural Products, Inc.

Long Beach, California 90805 USA

PRINCIPAL DISPLAY PANEL - 68 g Tube Box

Odor-Free

**EARTH'S
CARE™**

*NON-GREASY
FORMULA*

**Arthritis
Cream**

High Potency

*Capsaicin 0.1%
Penetrating relief for
joint and muscle pain*

**with Natural Rice Bran
and Almond Oil**

External Analgesic

**1%
FOR THE
PLANET
MEMBER**

2.4 OZ. (68 g)

Caring for you. Caring for the earth.™

Earth's Care™ donates 1% of its worldwide revenue to organizations that work to preserve and protect the environment.



**EARTH'S
CARE™**



Arthritis Cream

Odor-Free



**EARTH'S
CARE™**



Arthritis Cream

High Potency

*Capsaicin 0.1%
Penetrating relief for
joint and muscle pain*

**with Natural Rice Bran
and Almond Oil**



Indications

Earth's Care Arthritis Cream with natural Capsaicin is a powerful treatment for minor aches and pains of the joints and muscles due to arthritis, backaches, strains, sprains and bruises. It works by penetrating deeply and reducing the sensation of pain in the affected area.

This proprietary formula features natural moisturizers like Rice Bran Extract, Almond Oil and Shea Butter and is suitable for everyday use. It is odorless and contains no parabens, phthalates or artificial colors.

earths-care.com

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Caring for you. Caring for the earth.™



External Analgesic



2.4 OZ. (68 g)

CLOSE CAP TIGHTLY AFTER USE.

Drug Facts

Active ingredient **Purpose**
Capsaicin 0.1%.....Topical analgesic

Uses temporarily relieves minor pain of muscles and joints associated with: ■ arthritis ■ simple backache ■ strains ■ sprains ■ bruises

Warnings

For external use only

When using this product ■ read leaflet inside carton before use ■ use only as directed ■ do not bandage tightly or cover treated area ■ do not use with a heating pad or other heat sources ■ avoid contact with eyes and mucous membranes ■ do not apply to wounds, damaged, broken or irritated skin ■ a temporary burning sensation may occur upon application but normally disappears within several days ■ if a severe

Drug Facts (Continued)

Inactive ingredients beeswax, *Butyrospermum parkii* (shea) butter, cetearyl glucoside, cetyl alcohol, citric acid, glycerin, glyceryl stearate, heptyl undecylenate, hydrogenated castor oil, *Oryza sativa* (rice) bran extract, phenoxyethanol, potassium sorbate, *Prunus amygdalus dulcis* (sweet almond) oil, purified water, sodium stearyl glutamate, sodium stearyl lactylate, stearic acid, xanthan gum

Origins

Capsaicin is derived from hot peppers of the Capsicum genus and was first isolated as an active ingredient in the late 1800's. Used topically, it is a potent natural analgesic with deep penetrating characteristics.

burning sensation occurs, stop use immediately and read important information on leaflet inside carton ■ do not expose the area treated with product to heat or direct sunlight ■ do not apply immediately before or after activities such as bathing, swimming, sunbathing or strenuous exercise

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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

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RETAIN CARTON FOR COMPLETE DRUG FACTS.

Almond Oil
 (*Prunus amygdalus dulcis*)



has been a valued emollient for centuries and is known for its nourishing and soothing properties. Natural Rice Bran Extract is sourced from the husk and inner germ of rice and contains phytosterols, Vitamin E and other anti-oxidants.



- No Animal Testing
- No Parabens
- No Artificial Colors or Fragrances
- No Petrolatum
- No Sodium Hydroxide (Lye)

LOT

EXP



P5152-FZX

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EARTH'S CARE ARTHRITIS

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24286-1559
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
SHEA BUTTER (UNII: K49155WL9Y)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HEPTYL UNDECYLENATE (UNII: W77QUB6GXO)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
RICE BRAN (UNII: R60QEP13IC)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ALMOND OIL (UNII: 66YXD4DKO9)	
WATER (UNII: 059QF0KO0R)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT3ILN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24286-1559-2	1 in 1 BOX	09/25/2013	
1		68 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	09/25/2013	

Labeler - DLC Laboratories, Inc. (093351930)**Establishment**

Name	Address	ID/FEI	Business Operations
DLC Laboratories, Inc.		093351930	MANUFACTURE(24286-1559) , LABEL(24286-1559)