

PURE RELIEF- capsaicin cream
Concept 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.

Pure Relief™

Drug Facts

Active ingredient

Capsicum Oleoresin 0.0625% (Containing Capsaicin 0.025%)

Purpose

Pain Relieving

Uses

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

- simple backache
- arthritis
- strains
- sprains

Warnings

For external use only.

- do not apply to wounds or damaged skin
- do not bandage tightly
- do not use with heating pad, wrap, hot water bottle or any heating element.

When using this product avoid eye contact

- avoid contact with mucous membranes

Stop use and ask a doctor if condition worsens

- if symptoms persist for more than 7 days
- 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
- **if pregnant or nursing**, seek the advice of a health professional before using

Directions

- for adults only
- apply a thin layer to affected area not more than 4 times daily
- gently massage into the skin until fully absorbed
- wash hands with soap and water after each application to avoid spreading to sensitive mucous membranes

Other information

- Excess product can be removed with a soft cloth and cooking oil.
- If applying product to hands, wait 30 minutes before washing.
- Avoid water, heat, or direct sunlight while using product.
- If wearing contact lenses, insert prior to application and avoid touching them after applying product.
- If eye contact occurs, flush immediately with water.

Inactive ingredients

Water (Aqua), Butylene Glycol, Glycerin, Aloe Barbadensis Leaf Juice, Helianthus Annuus (Sunflower) Seed Oil, Medicago Sativa (Alfalfa) Extract, Arnica Montana Flower Extract, Cymbopogon Schoenanthus Stem/Leaf/Flower Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Mentha Piperita (Peppermint) Leaf Extract, Panax Ginseng Root Extract, Ginkgo Biloba Leaf Extract, Linum Usitatissimum (Linseed) Seed Extract, Celosia Argentea Seed Extract, Euterpe Oleracea Fruit Extract, Mentha Piperita (Peppermint) Oil, Glucosamine HCl, Dimethyl Sulfone, Hydrolyzed Corn Starch, Lauryl Laurate, Methyl Diisopropyl Propionamide, Ethyl Mentane Carboxamide, Menthyl Lactate, Hydrated Silica, Zea Mays (Corn) Starch, Hydrolyzed Corn Starch Octenylsuccinate, Cetearyl Isononanoate, Cetareth-20, Cetearyl Alcohol, Glyceryl Stearate, Cetareth-12, Cetyl Palmitate, Emu Oil, Polysorbate 20, Acrylates/C 10-30 Alkyl Acrylate Crosspolymer, Tocopheryl Acetate, Disodium EDTA, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Sodium Hydroxide.

Manufactured by Concept Laboratories, Inc.
Chicago, IL 60642 (USA) www.conceptlabs.org
#CL9783-R2

PRINCIPAL DISPLAY PANEL - 113 g Jar Label**EFFECTIVE RELIEF****PURE RELIEF™****PAIN RELIEVING CREAM**

WITH MOISTURIZING ALOE,
EMU OIL & GLUCOSAMINE

NET WT. 4 OZ (113 g)

Drug Facts

Active ingredient Purpose
 Capsicum Oleoresin 0.0825% Pain
 (Containing Capsaicin 0.025%) Relieving

Uses for the temporary relief of minor aches and pains of muscles and joints associated with
 ■ simple backache
 ■ arthritis ■ strains ■ sprains

Warnings

For external use only. ■ do not apply to wounds or damaged skin ■ do not bandage tightly ■ do not use with heating pad, wrap, hot water bottle or any heating element.

When using this product avoid eye contact
 ■ avoid contact with mucous membranes
 Stop use and ask a doctor if condition worsens ■ if symptoms persist for more than 7 days ■ 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
 ■ if pregnant or nursing, seek the advice of a health professional before using

EFFECTIVE RELIEF

PURE RELIEF™

PAIN RELIEVING CREAM

WITH MOISTURIZING ALOE,
 EMU OIL & GLUCOSAMINE
 NET WT. 4 OZ (113 g)

Directions

■ for adults only ■ apply a thin layer to affected area not more than 4 times daily ■ gently massage into the skin until fully absorbed ■ wash hands with soap and water after each application to avoid spreading to sensitive mucous membranes ■ A burning sensation may occur upon initial application but generally disappears with continued use. For a severe burning discomfort, remove excess product with a soft cloth and cooling oil.

Other information

■ Excess product can be removed with a soft cloth and cooling oil. ■ If applying product to hands, wait 30 minutes before washing. ■ Avoid water, heat, or direct sunlight while using product. ■ If wearing contact lenses, insert prior to application and avoid touching them after applying product. ■ If eye contact occurs, flush immediately with water.

Inactive ingredients

Water (Aqueous)
 Butylene Glycol, Glycerin, Aloe Barbadensis Leaf Juice, Helianthus Annuus (Sunflower) Seed Oil, Madecassoside, Salvia (Sage) Extract, Annona Montana Flower Extract, Cymbopogon Schoenanthus Stem Leaf Flower Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Mentha Piperita (Peppermint) Leaf Extract, Panax Ginseng Root Extract, Ginkgo Biloba Leaf Extract, Linum Usitatissimum (Flaxseed) Seed Extract, Calosia Argentea Seed Extract, Eurycea Oleracea Fruit Extract, Mentha Piperita (Peppermint) Oil, Glucosamine HCl, Dimethyl Sulfone, Hydrolyzed Corn Starch, Lauryl Laurate, Methyl Discrotyl Propionate, Ethyl Menthane Carboxamide, Menthyl Lactate, Hydrated Silica, Zea Mays (Corn) Starch, Hydrolyzed Corn Starch, Cholestanol, Cetylalcohol, Glyceryl Stearate, Ceteareth-12, Cetyl Palmitate, Emu Oil, Polyacrylate 20, Acrylates C-10-30 Alkyl Acrylate Crosspolymer, Tocopheryl Acetate, Disodium EDTA, Phenoxymethanol, Capryl Glycol, Ethylhexylglycerin, Hexylene Glycol, Sodium Hydroxide.

Manufactured by Concept Laboratories, Inc. #CUL165-PE
 Chicago, IL 60642 (USA) www.conceptlabs.org

PURE RELIEF

capsaicin cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:64058-356

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Capsaicin (UNII: S07O44R1ZM) (Capsaicin - UNII:S07O44R1ZM)	Capsaicin	2.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)	
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
LAURYL LAURATE (UNII: GPW77G0937)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	

GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ALFALFA (UNII: DJO934BRBD)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CYMBOPOGON SCHOENANTHUS TOP (UNII: 9SJ1LW39W)	
ROSEMARY (UNII: IJ67X351P9)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
GINKGO (UNII: 19FUJ2C58T)	
FLAX SEED (UNII: 4110YT348C)	
CELOSIA ARGENTEA SEED (UNII: O1H314U8M2)	
ACAI (UNII: 46AM2VJ0AW)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
EMU OIL (UNII: 344821WD61)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Hexylene Glycol (UNII: KEH0A3F75J)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64058-356-34	113 g in 1 JAR; Type 0: Not a Combination Product	12/06/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	12/06/2016	

Labeler - Concept Laboratories, Inc. (962282612)

Establishment

Name	Address	ID/FEI	Business Operations
Concept Laboratories, Inc.		962282612	MANUFACTURE(64058-356)