PENETREX(R) ARTHRITIS PAIN RELIEF- capsaicin cream Allure Labs

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Drug Facts

Active ingredient

Capsaicin 0.025%

Purpose

Topical analgesic

Uses

Temporarily relieves minor pains of muscles and joints associated with arthritis, simple backache, muscle strains, bruises, sprains, cramps

Warnings

For external use only

Do not use

on wounds, damaged, or irritated skin

with a heating pad

if you are alergic to capsicum or chili peppers

When using this product

Read directions befbre using

use only as directed; read and follow all directions and warnings on this carton rare cases of serious bums have been reported with products of this type

do not bandage tightly or apply local heat (such as heating pads) to the area of use avoid contact with eyes and mucous membranes

do not apply to wounds or damaged, broken or irritated skin

a transient burning sensation may occur upon application but generally disappears in several days

if severe burning occurs, discontinue use immediately

do not expose the area treated With product to heat or direct sunlight

do not use at the same time as other topical analgesics,

Stop use and ask a doctor if

condition worsens

redness is present

irritation develops

symptoms persist for more than 7 days or clear up and occur again within a few days you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

Keep out of reach of children.

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

Directions:

Adults and children 18 years of age and older:

apply to affected area but no more than 3 to 4 times daily

massage onto painful area until thoroughly absorbed

IF MEDICINE COMES IN CONTACT WITH HANDS, WASH WITH SOAP AND WATER

Children under 18 years of age: ask a doctor

If pregnant or breast-feeding, ask a health professional before use

Inactive ingredients:

Water (Aqua), Helanthus Annuus (Sunflower) Seed Oil, Glycerin, Glyceryl Stearates, Amica Montana Flower Extract,

Cetearyl Alcohol, Ceteareth-20, PEG-100 Stearate, Butyrospermum Parkii (Shea) Buffer, Cetyl Esters, Ammonium Acryloyldimethyltaurate/VP Copolymer, Aloe Barbadensis Leaf Juice, Dimethicone, Ethoxydiglycol, Phenoxyethanol,

Methyl Gluceth-20, Menthe Piperita Oil, Camphor, Ethylhexylglycerin, Potassium Sorbate, Glucosamine HCI, Choline Bitartrate,

Pyridoxine HCL, Glycyrrhizinate Dipotassium, Methyl sulfonyl Methane, Disodium EDTA, Boswellia carterii oil,

Sodium Benzoate, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Tocopherol, Citric Acid, Beta-Sitosterol, Squalene.



PENETREX(R) ARTHRITIS PAIN RELIEF

capsaicin cream

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:62742-4216 Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM) CAPSAICIN 0.025 g in 100 g

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| TEA TREE OIL (UNII: VIF565UC2G) | | |
| AMMONIUM ACRYLOYLDIMETHYLTAURATE (UNII: KBC00G95HI) | | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | | |
| CAMPHOR (NATURAL) (UNII: N20HL7Q941) | | |
| FRANKINCENSE OIL (UNII: 67ZYA5T02K) | | |
| TOCOPHEROL (UNII: R0ZB2556P8) | | |
| SUNFLOWER OIL (UNII: 3W1JG795YI) | | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | | |

PEG-100 STEARATE (UNII: YD01N1999R) SHEA BUTTER (UNII: K49155WL9Y) PEPPERMINT OIL (UNII: AV092KU4JH) **GLUCOSAMINE HYDROCHLORIDE** (UNII: 750W5330FY) **PYRIDOXINE HYDROCHLORIDE** (UNII: 68Y4CF58BV) POTASSIUM SORBATE (UNII: 1VPU26JZZ4) WATER (UNII: 059QF0KO0R) GLYCERIN (UNII: PDC6A3C0OX) ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) **GLYCYRRHIZINATE DIPOTASSIUM** (UNII: CA2Y0FE3FX) EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) **GLYCERYL MONOSTEARATE** (UNII: 2300U9XXE4) PHENOXYETHANOL (UNII: HIE492ZZ3T) POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY) **DIMETHICONE** (UNII: 92RU3N3Y10) CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) **SODIUM BENZOATE** (UNII: OJ245FE5EU) **DIETHYLENE GLYCOL MONOETHYL ETHER** (UNII: A1A1I8X02B) CHOLINE BITARTRATE (UNII: 6K2W7T9V6Y) .BETA.-SITOSTEROL (UNII: S347WMO6M4) **SQUALENE** (UNII: 7QWM220FJH) CETYL ESTERS WAX (UNII: D072FFP9GU) METHYL GLUCETH-20 (UNII: J3QD0LD11P) ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ) **DIMETHYL SULFONE** (UNII: 9H4PO4Z4FT)

| Packaging | | | | |
|-----------|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:62742- 4216-2 | 1 in 1 CARTON | 06/20/2022 | |
| 1 | NDC:62742- 4216-1 | 57 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 |
| unapproved drug other | | 06/20/2022 | |
| | | | |

Labeler - Allure Labs (926831603)

Registrant - Allure Labs (926831603)

| Establishmen | nt | | |
|--------------|---------|--------|---------------------|
| Name | Address | ID/FEI | Business Operations |

| Allure Labs | 926831603 | manufacture(62742-4216) |
|-------------|-----------|-------------------------|

Revised: 6/2022 Allure Labs