

PURE RELIEF PENETRATING PAIN RELIEF- capsaicin gel
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
Penetrating Pain Relief Spray

Drug Facts

| Active ingredient | Purpose |
|---|-------------------|
| Capsicum Oleoresin 0.0625% (Containing Capsaicin 0.025%) | 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

When using this product do not get into eyes

- do not bandage tightly
- do not use with heating pad, wrap, hot water bottle or any heating element.

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

- Children under 12 years of age consult a physician
- Apply a thin layer to affected area not more than 3 to 4 times daily
- Gently massage into the skin until fully absorbed
- Wash hands with soap and water after each application to avoid spreading to the eyes or other 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 cooking oil.

Inactive ingredients

Water (Aqua), Glycerin, PEG-75 Lanolin, Aloe Barbadensis Leaf Juice, PEG-40 Hydrogenated Castor Oil, Carbomer, Triethanolamine, Glucosamine HCl, Medicago Sativa (Alfalfa) Extract, Ginkgo Biloba Leaf Extract, Cymbopogon Schoenanthus Extract, Seed of Celosia Argentea Extract, Dimethyl Sulfone, Panax Ginseng Root Extract, Polysorbate 20, Tocopheryl Acetate, Emu Oil, Propylene Glycol, DMDM Hydantoin, Methylparaben, Propylparaben.

Questions or comments?

Call toll-free 1-888-373-8831

Manufactured by:
Concept Laboratories, Inc.
Chicago, IL 60642 (USA)
#CL10010

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

Pure Relief

**Penetrating
Pain Relief Spray
with Capsaicin**

**Temporary relieves
joint & arthritis pain in**

- **Hips**
- **Knees & Elbows**
- **Hands & Feet**
- **And more**

4 FL OZ (118mL)

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PURE RELIEF PENETRATING PAIN RELIEF

capsaicin gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:64058-118 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------------|
| Capsaicin (UNII: S07O44R1ZM) (Capsaicin - UNII:S07O44R1ZM) | Capsaicin | 0.0295 g in 118 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| Water (UNII: 059QF0KO0R) | |
| Glycerin (UNII: PDC6A3C0OX) | |
| PEG-75 LANOLIN (UNII: 09179OX7TB) | |
| DIMETHYL SULFONE (UNII: 9H4PO4Z4FT) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ALFALFA LEAF (UNII: HY3L927V6M) | |
| CYMBOPOGON SCHOENANTHUS LEAF (UNII: XF54B1Z2HF) | |
| GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY) | |

| | |
|---|--|
| GINKGO (UNII: 19FUJ2C58T) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| EMU OIL (UNII: 344821WD61) | |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| METHYLPARABEN (UNII: A2I8C7H9T) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| ASIAN GINSENG (UNII: CUQ3A77YXI) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:64058-118-14 | 118 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 12/06/2013 | |

Labeler - Concept Laboratories, Inc. (962282612)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------|
| Concept Laboratories, Inc. | | 962282612 | MANUFACTURE(64058-118) |

Revised: 2/2014

Concept Laboratories, Inc.