

**FAST ARTHRITIS AID PAIN RELIEVING- 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.*

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**FAST ARTHRITIS AID PAIN RELIEVING GEL**

Drug Facts

**Active Ingredient**

Capsicum Oleoresin 0.0625% (contains 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 bruises

**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 do not get into eyes

avoid contact with other mucous membranes

Discontinue use and ask a doctor if condition worsens or if symptoms persist for more than 7 days or 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

**Other information**

It is recommended to test for skin sensitivity prior to use. Apply product to a small area, follow the directions and wait 24 hours. Proceed with application if no adverse reaction. 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.

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), Glycerin, PEG-75 Lanolin, Aloe Barbadensis Leaf Juice, PEG-40 Hydrogenated Castor Oil, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Polysorbate 20, Glucosamine HCl, Emu Oil, Dimethyl Sulfone, Celosia Argentea Seed Extract, Ginkgo Biloba Extract, Panax Ginseng Root Extract, Medicago Sativa (Alfalfa) Extract, Cymbopogon Schoenanthus Extract, Tocopheryl Acetate, DMDM Hydantoin, Propylene Glycol, Methylparaben, Propylparaben.

### **Questions or comments?**

Call 1-888-373-8831 or visit [www.conceptlabs.org](http://www.conceptlabs.org)

Manufactured by Concept Laboratories, Inc.

Chicago, IL 60642 [www.conceptlabs.org](http://www.conceptlabs.org)

#BG-CL9734

### **PRINCIPAL DISPLAY PANEL - 57 g Bottle Label**

NDC 64058-413-42

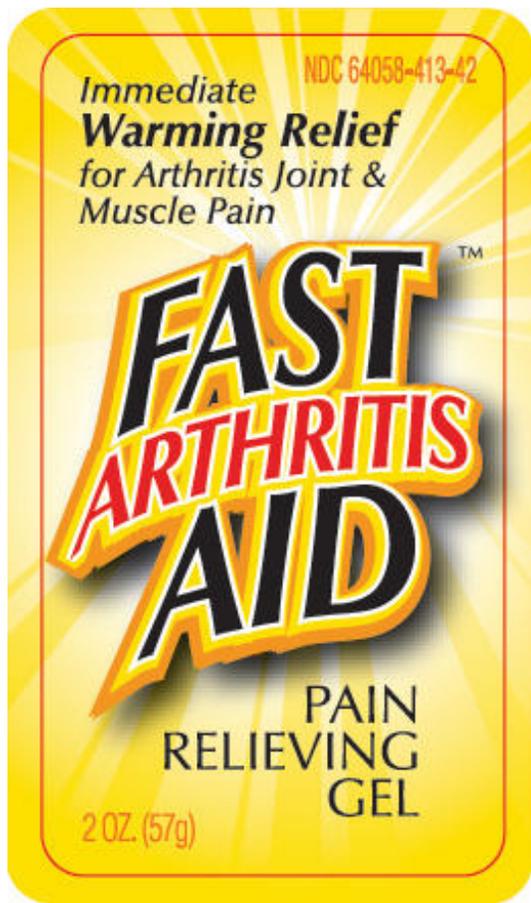
Immediate Warming Relief

For Arthritis Joint and Muscle Pain

Fast Arthritis Aid

Pain Relieving Gel

2 oz (57g)



|  |  |
|--|--|
| <b>Drug Facts</b>  |  |
| <b>Active ingredient Purpose</b>   |  |
| Capsicum<br>Oleoresin 0.0625%  |  |
| <b>Warnings</b>  |  |
| For external use only. ■ do not apply to wounds or damaged skin  |  |
| Keep out of reach of children. See Drug Facts label on outer packaging for complete Uses, Warnings and Directions. |  |
| <b>Directions</b>  |  |
| ■ Apply a thin layer to affected area not more than 3 to 4 times daily   |  |
| ■ Wash hands with soap and water   |  |
| <b>Inactive ingredients</b>  |  |
| See Drug Facts label on outer packaging  |  |
| Concept Laboratories, Inc. #CL9734<br>Chicago, IL 60642 www.conceptlabs.org  |  |

## FAST ARTHRITIS AID PAIN RELIEVING

capsaicin gel

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:64058-413 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength          |
|--|-------------------|-------------------|
| Capsaicin (UNII: S07O44R1ZM) (Capsaicin - UNII:S07O44R1ZM) | Capsaicin         | 0.01425 g in 57 g |

### 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)              |          |
| MEDICAGO SATIVA LEAF (UNII: HY3L927V6M)        |          |
| CYMOPOGON SCHOENANTHUS LEAF (UNII: XF54B1Z2HF) |          |
| GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY)   |          |

|  |
|--|
| <b>GINKGO</b> (UNII: 19FUJ2C58T)           |
| <b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)   |
| <b>EMU OIL</b> (UNII: 344821WD61)          |
| <b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)   |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3) |
| <b>METHYL PARABEN</b> (UNII: A2I8C7H9T)    |
| <b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)   |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:64058-413-42 | 57 g in 1 BOTTLE    |                      |                    |
| 2 | NDC:64058-413-44 | 113 g in 1 BOTTLE   |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part348                                  | 08/05/2011           |                    |

**Labeler** - Concept Laboratories, Inc. (962282612)

### Establishment

| Name                       | Address | ID/FEI    | Business Operations    |
|----------------------------|---------|-----------|------------------------|
| Concept Laboratories, Inc. |         | 962282612 | MANUFACTURE(64058-413) |

Revised: 1/2012

Concept Laboratories, Inc.