

ELGIN PAIN RELIEF- menthol gel
Eco-Logics, 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.

OTC-ACTIVE INGREDIENT SECTION

Active Ingredients Purpose

Menthol USP 3.5%..... Topical Analgesic

Menthol USP 3.5% Topical Analgesic

Uses

Uses:

Temporary relief from minor pains of sore muscles and joints associated with arthritis, backache, strains, and sprains..

Warning

WARNING:

For external use only.

Directions

Directions

Adults and children 2 years of age and older:

Apply to painful muscles and joint. Gently massage thoroughly into affected area.

Repeat as necessary but not more than 4 times daily.

Ask a doctor before use if you have:

Ask a doctor before use if you have Sensitive skin.

When Using this Product:

When Using this product:

Avoid contact with the eyes or mucous membranes

Do not apply to wounds or damaged skin

Do not use with other ointments, creams, sprays, or liniments.

Do not apply to irritated skin or if excessive irritation develops

Do not bandage

Wash hands after use with cool water

Do not use with heating pad or device.

Stop Use and Ask Doctor If:

Stop Use and Ask Doctor If: Condition worsens, or if symptoms persist for more than 7 days, or clear up and reoccur.

If pregnant or breast feeding:

If Pregnant or breast feeding: Ask a health professional before use.

Keep out of reach of children.

Keep out of reach of children. If accidentally ingested, get medical help or contact a Poison Control Center immediately.

immediate aqueous (Deionized filtered water) blend of certified * Organic Aloe Barbadensis Extract, Isopropyl Alcohol, *Ilex Paraguariensis leaf extract, Cinnamomum Camphora (camphor), Tocopheryl Acetate (Vitamin E Acetate), Carbomer, FD&C Blue #1, FD&C Yellow #5, Methylparaben, Triethanolamine.

Directions:

Directions:

Adults and children 2 years of age and older

Apply to painful muscles and joints. Gently massage thoroughly into affected area.

Repeat as necessary but not more than 4 times daily.

Other information:

Other Information: Store in a cool dry place with lid closed tightly.

Inactive Ingredients

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Aqueous (Deionized filtered water) blend of certified * Organic Aloe Barbadensis Extract, Isopropyl Alcohol, *Ilex Paraguariensis Leaf Extract, Cinnamomum Camphora (camphor), Tocopheryl Acetate (Vitamin E Acetate), Carbomer, FDC Blue #1, FDC Yellow #5, Methylparaben, Triethanolamine.

Drug Facts

Active Ingredients **Purpose**
Menthol USP 2.5% Topical Anesthetic

Uses: Temporary relief from minor aches and pains of sore muscles and joints associated with arthritis, backache, strains, and sprains.

Warnings: For external use only.

Flammable: Keep away from excessive heat or open flame.

Ask a doctor before use if you have: Sensitive skin

When Using This Product:

- Avoid contact with the eyes or mucous membranes
- Do not apply to wounds or damaged skin
- Do not use with other ointments, creams, sprays or liniments
- Do not apply to irritated skin or if excessive irritation develops
- Do not bandage
- Wash hands after use with cool water
- Do not use with heating pad or device

Stop Use and Ask A Doctor If: Condition worsens, or if symptoms persist for more than 7 days, or clear up and reoccur.

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Directions

Adults and children 2 years of age and older:

- Apply to painful muscles and joint. Gently massage thoroughly into affected area.
- Repeat as necessary but not more than 4 times daily.

Other Information: Store in a cool dry place with lid closed tightly.

Inactive Ingredients:
Aqueous (Deionized filtered water) blend of:
*Organic Aloe Barbadensis Extract, Isopropyl Alcohol, *Ilex Paraguariensis Leaf Extract, Cinnamomum Camphora (Camphor), Tocopheryl Acetate (Vitamin E Acetate), Carboxymethyl Cellulose (CMC), FD&C Blue #1, FD&C Yellow #5, Methylparaben, Methoparaben.

*This symbol before the ingredient indicates organic.

Mfg. for:
www.elginex.com
800-279-3782

ELGIN PAIN RELIEF

menthol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:30056-004 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 35 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CAMPHOR (NATURAL) (UNII: N20HL7Q941) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F) | |
| ALPHA-TOCOPHEROL (UNII: H4N855PNZ1) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:30056-004-03 | 85 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 07/11/2016 | |
| 2 | NDC:30056-004-04 | 113.4 g in 1 TUBE; Type 0: Not a Combination Product | 07/11/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 07/11/2016 | |

Labeler - Eco-Logics, Inc. (047667022)

Registrant - Elginex Corporation (005142799)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|------------------------|
| Natural Essentials, Inc. | | 947484713 | manufacture(30056-004) |

Revised: 5/2023

Eco-Logics, Inc.