

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

Warnings

For External Use only.

OTC ASK DOCTOR

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 limiments.

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.

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.

Other Information:

Store in a cool dry place with lid closed tightly.

Inactive Ingredients:

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

Dosage and Administration

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.

USES

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

**MUSCLE, JOINT & ARTHRITIS PAIN RELIEF
DEEP PENETRATING GEL**



CRYOTHERAPY FORMULA WITH ORGANIC ILEX, ORGANIC ALOE & VITAMIN E
• Stain-Free • Greaseless • Vanishing Scent

32 Fl. Oz. (877 g)





Drug Facts	Purpose
Active Ingredients Menthol USP 3.5%	Topical Analgesic
Uses: Temporary relief from minor aches and pains or 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:	
<ul style="list-style-type: none"> • 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 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 recur.	
If pregnant or breast feeding: Ask a health professional before use.	
Keep out of reach of children. If accidentally ingested, get medical help or contact a Poison Control Center immediately.	
Directions	
Adults and children 2 years of age and older:	
<ul style="list-style-type: none"> • 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 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.	


*This symbol before the ingredient indicates organic.

NDC 30066-004-02


Mfg. for:
www.elginex.com
800-279-3762



0 11280 00070 3


MADE IN THE USA

**MUSCLE, JOINT & ARTHRITIS PAIN RELIEF
DEEP PENETRATING GEL**



CRYOTHERAPY FORMULA WITH ORGANIC ILEX, ORGANIC ALOE & VITAMIN E
• Stain-Free • Greaseless • Vanishing Scent

16 FL. Oz. (454g)

ELGINEX
CORPORATION
www.elginex.com

Drug Facts

Active Ingredients	Purpose
Menthol USP 3.5%	Topical Anesthetic

Uses: Temporary relief from minor aches and pains or 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.

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

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

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 Barbadosensis 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.

*This symbol before the ingredient indicates organic.

NDC 30056-004-00

Mfg. for: www.elginex.com
800-279-3762



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: 1Q953B4O4F)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0K00R)	

CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30056-004-28	3780 g in 1 JUG; Type 0: Not a Combination Product	07/11/2016	
2	NDC:30056-004-32	877 g in 1 BOTTLE, PUMP; 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: 11/2019

Eco-Logics, Inc.