

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

Purpose

Menthol USP 3.5%Topical Analgesic

Uses

USES:

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

Warning

Warning

For external Use only.

Directions

ADirections:

Adults and children 2 years of age and older:

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

Repeat as necessary but not more than 4 times daily.

Ask doctor before use if you:

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 linaments.

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:

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

Keep out of reach of children:

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

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

Inactive Ingredients:

Aqueous (Deionized 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.

If pregnant or breast feeding:

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

Principle Display Panel

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



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

32 FL. Oz. (877 g)



Drug Facts	
Active Ingredients	Purpose
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 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: <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 30069-000-02

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



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



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

16 FL. Oz. (454g)



Drug Facts	
Active Ingredients	Purpose
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 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: <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 *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 30069-000-01

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



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: 059QF0KO0R)	
CARBOMER HOMOPOLYMER 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: 5/2023

Eco-Logics, Inc.