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 Ingedients 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:

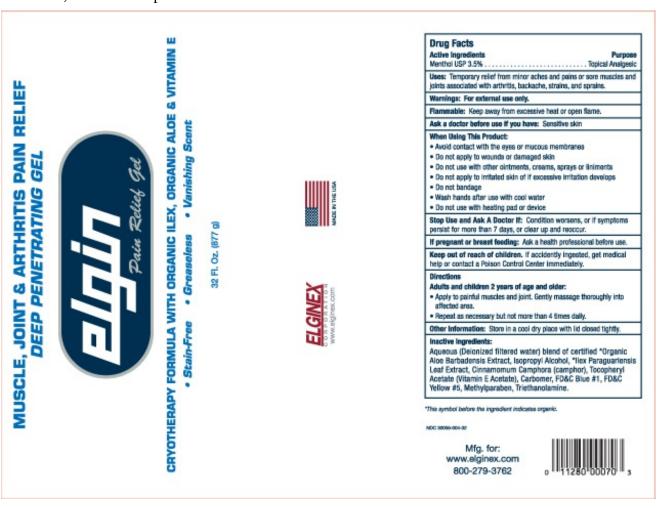
Adults and children 2 years of age and older

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

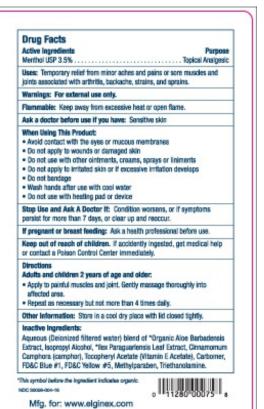
Repeat as necessary but not more than 4 times daily.

USES

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







ELGIN PAIN RELIEF

menthol gel

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

800-279-3762

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	35 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)		
METHYLPARABEN (UNII: A218 C7HI9 T)		
TROLAMINE (UNII: 9O3K93S3TK)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
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-	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.