

ICE ANALGESIC- menthol gel

Filo America

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.

ICE ANALGESIC GEL

ICE ANALGESIC GEL

Active Ingredient

Menthol 1.0%

Purpose

Topical Analgesic

Uses

Temporary relief:

minor muscles aches and pains

Warnings

For external use only. Avoid contact with eyes.

Ask a doctor before use if you have cough associated with

- smoking
- excessive phlegm
- asthma
- emphysema
- persistent or chronic cough

When using this product do not

- heat
- microwave
- add to hot water or any container where heating water may cause splattering and result in burns
- use in eyes or directly on mucous membranes
- take by mouth or place in nostrils
- apply to wounds or damaged skin
- bandage skin

Consult a doctor and discontinue use

if condition worsens, persists for more than 1 week or tends to recur

Keep out of reach of children.

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions

For the temporary relief of minor muscle aches and pains

see important warnings under "When using this product"

- not for use on children under 2 years of age
- adults and children 2 years of age and older: apply to painful area and massage until gel is absorbed into the skin, repeat 3 to 4 times daily

Inactive Ingredients

blue 1, camphor, carbomer, isopropyl alcohol, methylchloroisothiazolinone, methuyliothiazoline, sodium hydroxide, water

ICE Analgesic Gel

Net wt 8oz (227g)

DISTRIBUTED BY:

Filo America

P.O. Box 23592

Los Angeles, CA 90023

Developed in USA, products in PRC

questions or concerns?

1.866.460.0322

ASSURED ICE COLD TOPICAL ANALGESIC GEL 8oz (33992-7994-8)





ICE

ANALGESIC GEL

NET WT. 8 OZ (227 G)

规格 20x4.7cm

Drug Facts

Active Ingredient:

Menthol, 1.0%.....

Purpose

Topical analgesic

Uses; temporarily relieves:

- Minor muscle aches and pains

Warning: For external use only; avoid contact with eyes. Ask a doctor before use if you have cough associated with • smoking • excessive phlegm • asthma • emphysema • persistent or chronic cough

When using this product, do not; heat • microwave • add to hot water or any container where heating water may cause splattering and result in burns • use in eyes or directly on mucous membranes • take by mouth or place in nostrils • apply to wounds or damaged skin • bandage skin

Consult a doctor and discontinue use; if condition worsens, persists for more than 1 week or tends to recur.

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

DIRECTIONS:

For the temporary relief of minor muscle aches and pains.

See important warnings under "When using this product"

- not for use on children under 2 years of age
- adults & children 2 years & older: Apply liberally to painful area and massage until gel is absorbed into the skin. Repeat 3 to 4 times daily.

Inactive Ingredients:

Blue 1, Camphor, Carbomer, Isopropyl Alcohol, Methylchloroisoethiazolinone, Methylisothiazolinone, Sodium Hydroxide, Water.

Distributed by:

Filo America

P.O. Box 23592

Los Angeles, CA 90023

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ICE ANALGESIC

menthol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:50438-501

Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.0 g in 100 g	
Inactive Ingredients				
	Ingredient Name	Strength		
	CAMPHOR (NATURAL) (UNII: N20HL7Q941)			
	ALCOHOL (UNII: 3K9958V90M)			
	FD&C BLUE NO. 1 (UNII: HBR47K3TBD)			
	ISOPROPYL ALCOHOL (UNII: ND2M416302)			
	METHYLCHLORO ISO THIAZOLINONE (UNII: DEL7T5QRPN)			
	SODIUM HYDROXIDE (UNII: 55X04QC32I)			
	WATER (UNII: 059QF0KO0R)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50438-501-01	227 g in 1 JAR; Type 0: Not a Combination Product		
Marketing Information				
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	OTC monograph not final	part348	05/05/2015	

Labeler - Filo America (943873703)

Registrant - Ningbo Pulisi Daily Chemical Products Co., Ltd. (529047265)

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Pulisi Daily Chemical Products Co., Ltd.		529047265	manufacture(50438-501)

Revised: 5/2015

Filo America