

ASSURED ICE COLD TOPICAL ANALGESIC - menthol gel
Greenbrier International, 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.

ASSURED ICE COLD TOPICAL ANALGESIC GEL

ASSURED ICE COLD TOPICAL ANALGESIC GEL

Active Ingredient

Menthol 1.25%

Purpose

Topical Analgesic

Uses

for the temporary relief of minor aches and pains of muscles and joints

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, persist 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

- see important warnings under "When using this product"
- adults and children 2 years of age and older: apply to the affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a physician.

Other information

store at 20 to 25 degreesC (68 to 77degrees F)

Inactive Ingredients

camphor, carbomer, ethyl alcohol, FDandC blue no.1, isopropyl alcohol, methylchloroisoethiazolinone, methylisothiazolinone, sodium hydroxide, water.

Assured ICE COLD

Topical Analgesic Gel

Net wt 8oz (227g)

DISTRIBUTED BY:

GREENBRIER INTERNATIONAL, INC.

CHESAPEAKE, VA 23320

MADE IN CHINA

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

ASSURED ICE COLD
TOPICAL ANALGESIC GEL
NET WT. 8 OZ (227g)

Drug Facts
Purpose Topical analgesic.
Active ingredients: Menthol 1.25%
Uses: For the temporary relief of minor aches and pains of muscles and joints.
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: see important warnings under "When using this product"
• adults & children 2 years of age & older: apply to the affected area not more than 3 to 4 times daily
• children under 2 years of age: consult a physician.
Other information: store at 20° to 25°C (68° to 77°F)
Inactive ingredients: camphor, carbomer, ethyl alcohol, FD&C blue no. 1, isopropyl alcohol, methylchloroisoethiazolinone, methylisothiazolinone, sodium hydroxide, water.

ASSURED ICE COLD TOPICAL ANALGESIC

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-7994
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.25 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)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-7994-8	227 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/06/2011	

Labeler - Greenbrier International, Inc. (610322518)**Registrant** - Ningbo Unichem Household Products Co., Ltd. (528196956)**Establishment**

Name	Address	ID/FEI	Business Operations
Ningbo Unichem Household Products Co., Ltd.		528196956	manufacture(33992-7994)

Revised: 3/2013

Greenbrier International, Inc.