ASSURED ICE COLD TOPICAL ANALGESIC - camphor, 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

Active Ingredients

Camphor 3.0%

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 healing 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

carbomer, FD and C blue no. 1, isopropyl alcohol, methylchloroisothiasolinone, 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 camphor, menthol gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:33992-7993 Route of Administration TOPICAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	3.0 g in 100 g			
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.25 g in 100 g			

Inactive Ingredients	
Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:33992-7993-8	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)

Revised: 7/2011 Greenbrier International, Inc.