ICE COLD TOPICAL ANALGESIC GEL- 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.

Ice Cold Topical Analgesic Gel

Active Ingredient ***Purpose***

Menthol 1.25%.....Topical Analgesic

Uses

forthe temporary relief of minor aches and pains of muscles and joints.

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

Other information

- store at 20oC to 25oC (68o to 77oF)

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
- microwafe
- 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 worsesn, persists for more than 1 week or tends to recur.

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.

Inactive Ingredients

camphor, carbomer, ethyl alcohol, fd&c blue no.1, isopropyl alcohol, methylchloroisothiazolinone, methylisothiazolinone, sodium hydroxide, water.

ICE COLD TOPICAL ANALGESIC GEL

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:33992-3007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.84 mg in 227 mg

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
ALCOHOL (UNII: 3K9958V90M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:33992-3007-1	237 mg in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/24/2013	

Labeler - Greenbrier International, Inc. (610322518)

Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(33992-3007)

Revised: 4/2019 Greenbrier International, Inc.