

THERACARE ICE BLUE GEL PAIN RELIEVING- menthol gel

Veridian Healthcare

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.

Theracare Ice Blue Gel

Active ingredient

Menthol 2%

Purpose

Topical analgesic

Uses

- temporarily relieves minor aches and pains of muscles and joints associated with:
- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only

When Using this product

- with other topical pain relievers
- with heating pads or heating devices
- avoid contact with eyes
- do not bandage tightly
- do not apply to wounds or damage skin

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breast-feeding

ask a health professional before use

Keep Out of Reach of Children

If swallowed, get medical help or contact a Poison Control Center (800-222-1222) right away.

Directions

- clean affected area before applying product
- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor before using this product

Other information

- do not freeze
- store at room temperature
- keep container tightly closed when not in use
- do not use, pour, spill, or store near heat or open flame

Inactive ingredients

ammonium hydroxide, benzyl alcohol, carbopor 940, cupric sulfate, FD&C blue no. 1, isopropyl alcohol, magnesium sulfate, PEG-40 hydrogenated castor oil, sodium hydroxide, thymol, water

Questions or comments?

Customer care **866-326-1313**

Principal Display



THERACARE ICE BLUE GEL PAIN RELIEVING

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71101-217
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
AMMONIA (UNII: 5138Q19F1X)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
CUPRIC SULFATE (UNII: LRX7AJ16DT)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
THYMOL (UNII: 3J50XA376E)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71101-217-01	226.8 g in 1 JAR; Type 0: Not a Combination Product	01/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2022	

Labeler - Veridian Healthcare (830437997)

Establishment

Name	Address	ID/FEI	Business Operations
ANICARE PHARMACEUTICALS PRIVATE LIMITED		916837425	manufacture(71101-217)

