

HEALTH SMART BLUE ICE TOPICAL ANALGESIC- menthol and camphor gel Home Smart Products

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.

Health Smart Blue Ice Topical Gel

Active Ingredients

Menthol	1.0%
Camphor	0.5%

Purpose

Topical Analgesic

Uses

For the temporary relief of minor pains and aches of your muscles and joints associated with:

- Sports Injuries
- Sprains
- Arthritis
- Bruises

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

Do not use with heating devices or pads.

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 and children 2 years and over:

- apply to the affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a physician.

Inactive Ingredients

Aqua, Isopropyl Alcohol, Propylene Glycol, Carbopol, PEG-40 Hydrogenated Castor Oil, Sodium Hydroxide, Disodium EDTA, Benzyl Alcohol, BHT & FD&C Blue No.1

PRINCIPAL DISPLAY PANEL

HEALTH SMART BLUE ICE TOPICAL ANALGESIC GEL

NET WT.8 OZ (227g)



HEALTH SMART BLUE ICE TOPICAL ANALGESIC

menthol and camphor gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52862-017
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52862-017-27	127 g in 1 TUBE; Type 0: Not a Combination Product	08/01/2020	
2	NDC:52862-017-28	170 g in 1 TUBE; Type 0: Not a Combination Product	08/01/2020	
3	NDC:52862-017-21	170 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	
4	NDC:52862-017-29	227 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	
5	NDC:52862-017-30	300 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	
6	NDC:52862-017-26	500 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/02/2013	

Labeler - Home Smart Products (161872676)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(52862-017)