

HEMPVANA COLD AS ICE PAIN RELIEF- menthol gel
Telebrands Corp

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.

Hempvana Cold As Ice Pain Relief

Drug Facts

Active Ingredient:

Menthol USP 8% w/w

Purpose

Menthol USP 8% w/w.....Topical Analgesic

Uses

temporarily relief of minor aches and pains of muscles and joints associated with:

- simple backache • arthritis • strains • bruises • sprains

Warnings

For external use only

Flammable: Keep away from excessive heat or open flame

When using this product, avoid contact with eyes.

- Do not use in large quantities, particularly over raw surfaces or blistered areas.
- Do not apply to wounds or damaged skin
- Do not bandage tightly

Stop use and ask a doctor if

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

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults: Apply to affected are not more than 3 to 4 times daily. If produce comes in

HEMPVANA COLD AS ICE PAIN RELIEF

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73287-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	8 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
CALENDULA OFFICINALIS WHOLE (UNII: PFR03EBU0H)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MELISSA OFFICINALIS (UNII: YF70189L0N)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73287-004-01	1 in 1 CARTON	06/11/2019	
1		74 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/11/2019	

Labeler - Telebrands Corp (177266558)

Establishment

Name	Address	ID/FEI	Business Operations
A.I.G. TECHNOLOGIES, INC.		086365223	manufacture(73287-004)

Revised: 7/2021

Telebrands Corp