

MOUNTAIN ICE SPORTS PAIN RELIEF- menthol, camphor gel
Mountainside Medical Equipment, 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.

Mountain Ice Sports Recovery Gel

Active ingredients

Menthol 6%
Camphor 4%

Purpose

External Analgesic

Use:

Temporary relief of minor aches and pains of muscles and joints associated with osteoarthritis, rheumatoid arthritis, muscle strains, and sprains.

Warnings:

For external use only.

Flammable: keep away from excessive heat or open flame. Avoid contact with eyes or mucous membranes.

When using this product:

- Do not apply to wounds, damaged skin, or irritated skin.
- Do not apply with other creams, ointments, sprays or liniments.
- **Stop use and ask a doctor if:** Conditions worsen, skin irritation develops, or condition does not improve after 7 days, or clear up and recur.

Keep out the reach of children:

If accidentally swallowed get medical help or contact a Poison Control Center right away.

Directions:

Adults and children 2 years and older. Rub on the affected area evenly no more than 4 times per day. Children under 2 years: Consult with your doctor.

Inactive Ingredients:

Aloe Barbadensis Leaf Juice, Arnica Montana Flower Extract, Boswellia Serrata (Frankincense) Oil, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Curcuma Longa (Turmeric) Root Oil, Dimethyl Sulfone, Dipotassium Glycyrrhizate, Ethylhexylglycerin, Eucalyptus Globulus (Eucalyptus) Leaf Oil, Glycerin, Isopropyl Alcohol, L-Arginine, Limonene, Magnesium Sulfate, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Mentha Spicata (Spearmint) Oil, Niacinamide, Panax Ginseng Root Extract, Phenoxyethanol, Polysorbate 20, Tocopheryl Acetate, Triethanolamine, Water (Aqua), Blue 1 (CI 42090)

Package/Label Principal Display Panel

MUSCEL THERAPY GEL

MOUNTAIN ICE

SPORTS RECOVERY GEL

VEGAN

GLUTEN FREE \ | / GLUTEN FREE \ | /
MADE WITH NATURAL INGREDIENTS

MOUNTAIN ICE

32 FL OZ (946 ML)



Label

MOUNTAIN ICE SPORTS PAIN RELIEF

menthol, camphor gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72793-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	6 g in 100 mL
CAMPHOR OIL (UNII: 75IZZ8Y727) (CAMPHOR OIL - UNII:75IZZ8Y727)	CAMPHOR OIL	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE OIL (UNII: 5T1XCE6K8K)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
TURMERIC OIL (UNII: 6KGS8SP16U)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ARGININE (UNII: 94ZLA3W45F)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
TEA TREE OIL (UNII: VIF565UC2G)	
SPEARMINT OIL (UNII: C3M81465G5)	
NIACINAMIDE (UNII: 25X51I8RD4)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KOOR)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72793-200-01	6 mL in 1 PACKET; Type 0: Not a Combination Product	05/08/2020	
2	NDC:72793-200-02	30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/08/2020	06/14/2022
3	NDC:72793-200-03	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/08/2020	
4	NDC:72793-200-04	99 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	05/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/08/2020	

Labeler - Mountainside Medical Equipment, Inc. (119735871)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing, Inc.		793406000	MANUFACTURE(72793-200)

Revised: 6/2022

Mountainside Medical Equipment, Inc.