

**TERRAFREEZE PAIN RELIEF- menthol,methyl salicylate,histamine
dihydrochloride cream
Beyond Derma, LLC**

TerraFreeze Pain Relief Cream

Drug Facts

Active Ingredients

Menthol 10.00%

Methyl Salicylate 10.00%

Histamine DHCl 0.050%

Purpose

Topical Analgesic

Uses:

For the temporary relief of minor aches and pains of the muscles and joints associated with arthritis, simple backache, sprains, bruises and strains.

Warnings:

- For External use only
- Keep out of reach of children. If swallowed, consult physician.
- Do not apply to wounds or damaged skin.

When using this product

- Avoid contact with eyes. If product gets into eyes, rinse thoroughly with water
- Do not bandage tightly

Stop use and ask a doctor if:

- Rash appears
- If symptoms persist for more than seven days, discontinue use and consult physician

If pregnant or breastfeeding,

ask a healthcare professional before use.

Keep out of reach of children.

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

Directions

- Apply to affected area 3-4 times daily. **Adults and children two-years of age or older:**
- Consult a physician **Children under two-years of age:**

Other Information

- Store at room temperature with lid closed tightly.

Other Ingredients

Aloe Barbadensis (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Extract, Ascorbic Acid (Vitamin C), Boswellia Serrata Extract, Bromelain, Butylene Glycol, C13-14 Isoparaffin, Chamomilla Recutita (Chamomile) Extract, Citric Acid, Curcuma Longa (Turmeric) Extract, Emu Oil, Ethylhexylglycerin, Ethylhexyl Stearate, Glycyrrhiza Glabra (licorice) Root Extract, Helianthus Annuus (Sunflower) Oil, Laureth-7, magnesium Sulfate, Methylsulfonylmethane (MSM), Niacin, Phenoxyethanol, Polyacrylamide, Polysorbate-80, Potassium Sorbate, Sodium Polyacrylate, Tetrasodium EDTA, Tocopheryl Acetate (Vitamin E), Tricedeth-6, Zingiber Officinale (Ginger) Root Extract

Questions or Comments?

(support email address) or Call 1.855.977.0726

Package Labeling:



TERRAFREEZE PAIN RELIEF

menthol,methyl salicylate,histamine dihydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71805-855
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	100 mg in 1 g
HISTAMINE DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	0.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA (UNII: O80TY208ZW)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	

INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
BROMELAINS (UNII: U182GP2CF3)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
TURMERIC (UNII: 856YO1Z64F)	
EMU OIL (UNII: 344821WD61)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
LICORICE (UNII: 61ZBX54883)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
LAURETH-7 (UNII: Z95S6G8201)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
NIACIN (UNII: 2679MF687A)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
GINGER (UNII: C5529G5JPQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71805-855-00	1 in 1 BOX	10/12/2017	
1		57 g in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	10/12/2017	

Labeler - Beyond Derma, LLC (080699834)