

INSPIRATION ACADEMY MENTHOL COOLING PAIN CREAM- menthol 5 percent cream
Renu Laboratories, 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.

Inspiration Academy Menthol Cooling Pain Relief Cream

Active Ingredients:

Menthol 5%

Keep out of reach of children

If swallowed, get medical help or contact a poison control center right away.

Purpose

Topical Analgesic

Questions or Comments

PHONE: (941) 795-5466 (LION)

Stop use and ask a doctor if

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

When using this product:

- Do not bandage tightly
- avoid contact with eye
- do not apply to wounds or damaged skin
- do not use heating pads or other heating devices.

Directions:

adults and children 12 years of age and older

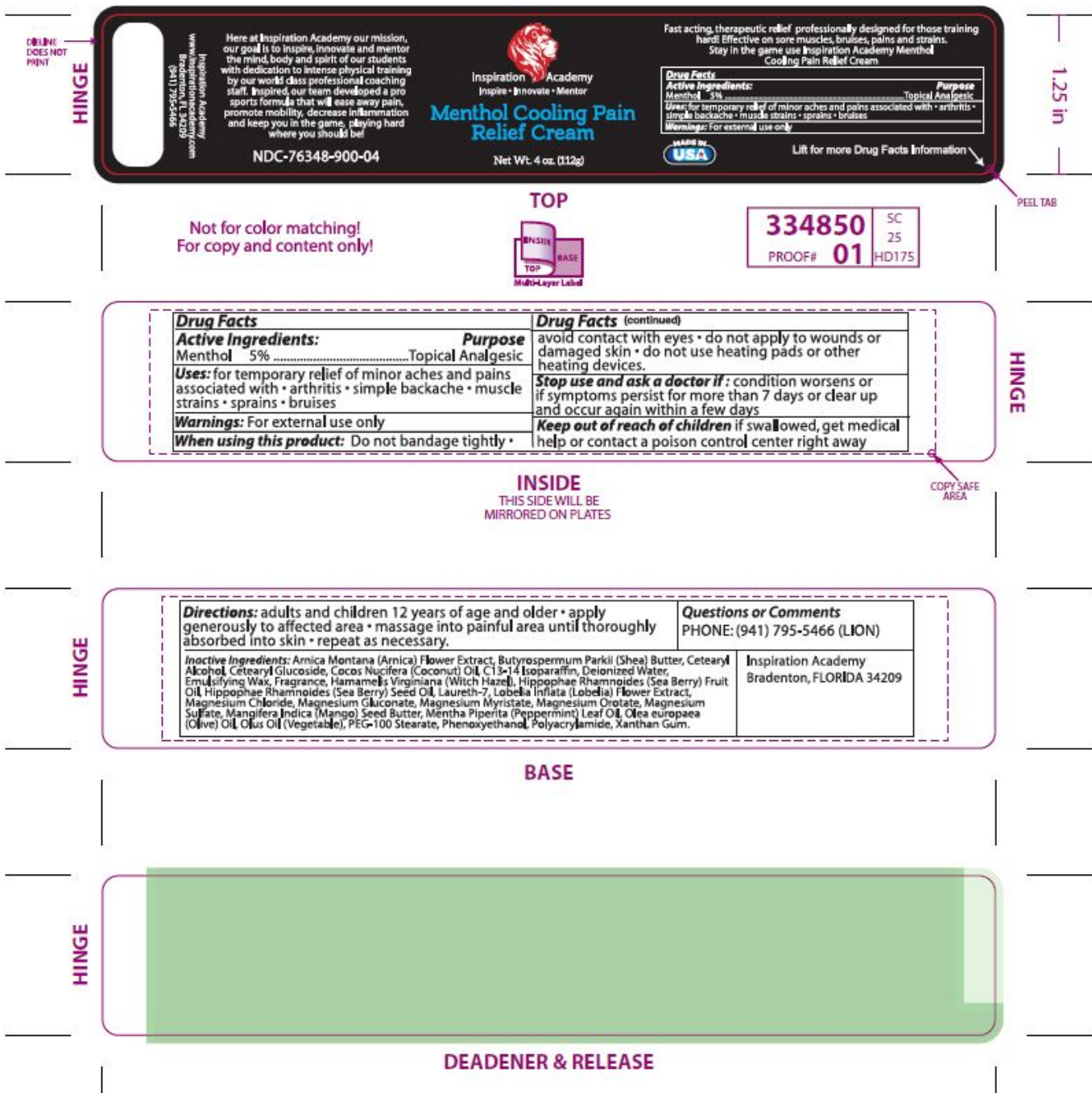
- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary

Arnica Montana (Arnica) Flower Extract, Butyrospermum Parkii (Shea) Butter,

Cetearyl Alcohol, Cetearyl Glucoside, Cocos Nucifera (Coconut) Oil, C13-14 Isoparaffin, Deionized Water,

Emulsifying Wax, Fragrance, Hamamelis Virginiana (Witch Hazel), Hippophae Rhamnoides (Sea Berry) Fruit and Seed Oil,

Laureth-7, Lobelia Inflata (Lobelia) Flower Extract, Magnesium Chloride, Magnesium Gluconate, Magnesium Myristate, Magnesium Orotate, Magnesium Sulfate, Mangifera Indica (Mango) Seed Butter, Mentha Piperita (Peppermint) Leaf Oil, Olea europaea (Olive) Oil,



INSPIRATION ACADEMY MENTHOL COOLING PAIN CREAM			
menthol 5 percent cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-900
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	5.6 g in 112 g

Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)	
PEG-100 STEARATE (UNII: YD01N1999R)	
HIPPOPHAE RHAMNOIDES FRUIT OIL (UNII: TA4JCF9S1J)	
SHEA BUTTER (UNII: K49155WL9Y)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
WATER (UNII: 059QF0KO0R)	
WHITE WAX (UNII: 7G1J5DA97F)	
WITCH HAZEL (UNII: 101I4J0U34)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
COCONUT OIL (UNII: Q9L0O73W7L)	
LAURETH-7 (UNII: Z95S6G8201)	
LOBELIA INFLATA (UNII: 9PP1T3TC5U)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
MAGNESIUM GLUCONATE (UNII: T42NAD2KHC)	
MAGNESIUM MYRISTATE (UNII: Z1917F0578)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
CORN OIL (UNII: 8470G57WFM)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MAGNESIUM OROTATE (UNII: GI96W46M5A)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-900-01	1 in 1 BOX	11/08/2021	
1	NDC:76348-900-04	112 g in 1 JAR; 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	11/08/2021	

Labeler - Renu Laboratories, Inc. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
RENU LABORATORIES, INC.		945739449	manufacture(76348-900)

Revised: 1/2022

Renu Laboratories, Inc.