

ARNICA PERFORMANCE GEL- arnica montana gel

Myo-Breathe,LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Drug Facts

Active Ingredient: Arnica Montana 15%

Purpose: Trauma, bruises, stiffness, muscle soreness

For relief of muscle aches and stiffness due to minor injuries such as strains, falls and blows. Reduces pain, swelling, and discoloration from bruises.

Warnings: For external use only.

Avoid contact with eyes and with open wounds. Do not use on broken skin

Stop use and ask a doctor if condition persists for more than 3 days or worsens.

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

Directions: Apply Arnica Performance Gel to affected area as soon as possible after minor injury.

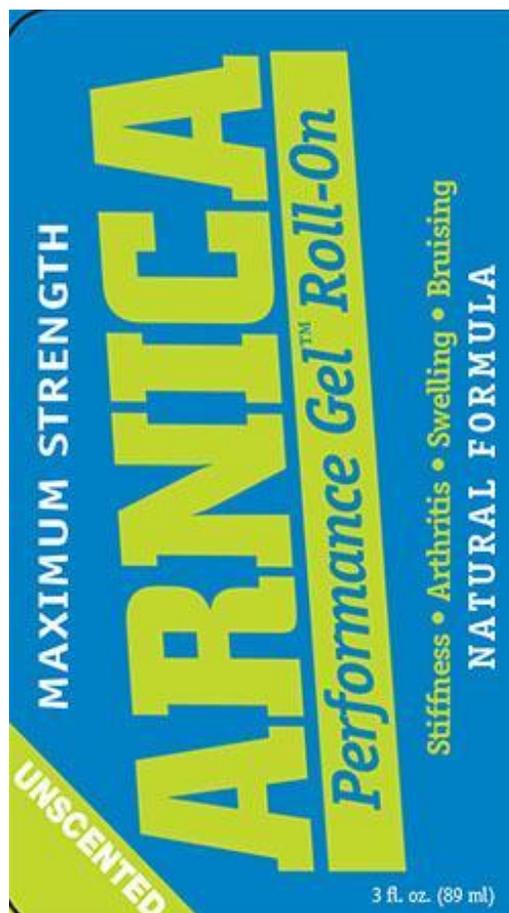
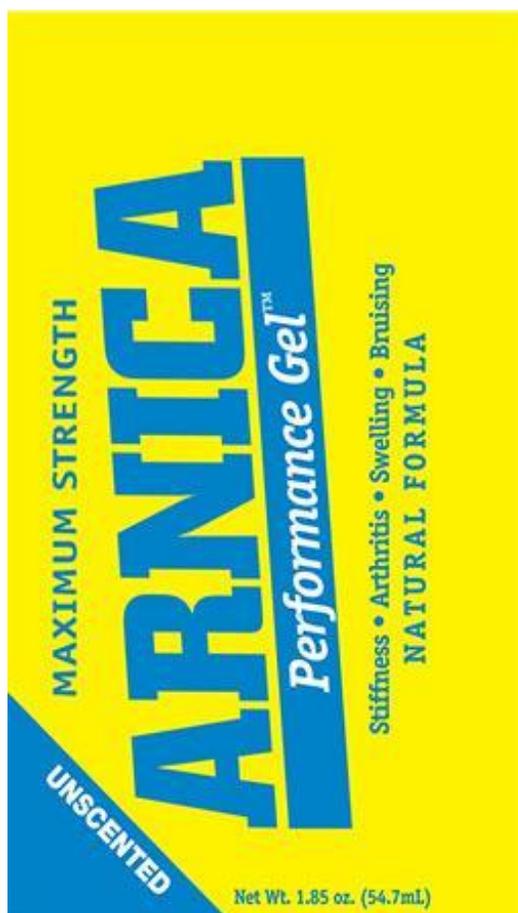
Repeat 3 times a day or as needed

Other Information: Store at 68-77 F (20-25 C)

Inactive Ingredients

Aloe Barbadensis, Caprylic /Capric Triglyceride, Caprylyl Glycol, Carbomer, Deionized Water, Glycerin, Ilex Paraguariensis Extract, Isopropyl Alcohol, Isodecyl Neopentanoate, Lecithin, MSM, Phenoxyethanol, Sorbic Acid, Triethanolamine & Vitamin E

Question or Comments? 1-800-803-1535



ARNICA PERFORMANCE GEL

arnica montana gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41391-121
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	150 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85)	
CARBOMER 934 (UNII: Z135WT9208)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	

LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBIC ACID (UNII: X045WJ989B)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41391-121-21	59 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:41391-121-20	89 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
unapproved drug other		06/25/2015	

Labeler - Myo-Breathe,LLC (003635412)

Revised: 7/2015

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