

**ARNICA PLUS- arnica montana, hamamelis virginiana, rhus tox, whey protein gel
Peaceful Mountain, Inc.**

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Drug Facts:

ACTIVE INGREDIENTS:

Arnica Montana 6X, 12X, Hamamelis Virginiana 6X, 12X, Rhus Tox 6X, 12X, Whey Protein 6X, 12X

INDICATIONS:

May temporarily relieve minor symptoms of sore, overexerted muscles.**

**These statements are based upon traditional homeopathic principles. They have not been reviewed by the Food and Drug Administration.

WARNINGS:

For external use only.

If pregnant or breast-feeding, ask a health professional before use.

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

When using this product • Do not get into eyes.

Stop use and ask a doctor if • Conditions worsens • Symptoms last more than 7 days

Do not use if safety seal is broken or missing.

KEEP OUT OF REACH OF CHILDREN:

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

DIRECTIONS:

Apply at least 3 times daily over the affected area.

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INACTIVE INGREDIENTS:

Purified Water, Vitis Vinifera (Grape Seed Oil), Whey Protein, Lecithin (Soy), Phenoxyethanol, Caprylyl Glycol, Sorbic Acid, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Arnica Montana (Flower), Aloe Barbadosensis Leaf, Salix Alba Bark (White Willow), Polysorbate 20, Hamamelis Virginiana Bark (Witch Hazel), Sodium Hydroxide, Ascorbic Acid, Harpagophytum Procumbens Root

(Devil's Claw), Tocopherols (Soy), Mentha Piperita Leaf (Peppermint), Edetate Disodium, Oregano, Potassium Sorbate

QUESTIONS:

Dist. by Peaceful Mountain, Inc.

Woodbine, IA 51579

888-303-3388

www.peacefulmountain.com

patent pending

PACKAGE LABEL DISPLAY:

peaceful mountain

THE HEIGHT OF HEALTH

arnica plus

homeopathic gel

paraben-free

organic and wild-crafted herbs

formulated in boulder, co

Net wt. 4 lbs. (64 oz.) (1.8 kg)

Inactive Ingredients: Purified Water, Vitis Vinifera (Grape) Seed Oil, Whey Protein Concentrate (milk), Lecithin (soy), Phenoxy-ethanol & Caprylyl Glycol & Sorbic Acid, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Arnica Montana (Arnica) Flower Extract, Aloe Barbadensis Leaf Juice, Salix Alba (White Willow) Bark Extract, Polysorbate 20, Hamamelis Virginiana (Witch Hazel) Bark Extract, Sodium Hydroxide, Ascorbic Acid, Harpagophytum Procumbens (Devil's Claw) Root Extract, Tocopherols (soy), Mentha Piperita (Peppermint) Leaf Extract, Edetate Disodium, Natural Plant Extract and Potassium Sorbate

unscented • non-greasy
no petroleum • no animal testing

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Lot: XXXXX

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THE HEIGHT OF HEALTH

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Active Ingredients: Arnica Montana 6x, 12x, Hamamelis Virginiana 6x, 12x, Rhus Tox 6x, 12x, Whey Protein 6x, 12x

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Directions: Apply at least 3 times daily over the affected area.

ARNICA PLUS

arnica montana, hamamelis virginiana, rhus tox, whey protein gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0065
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	6 [hp_X] in 1 g
HAMAMELIS VIRGINIANA BARK (UNII: IH3063S9MY) (HAMAMELIS VIRGINIANA BARK - UNII:IH3063S9MY)	HAMAMELIS VIRGINIANA BARK	6 [hp_X] in 1 g
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	6 [hp_X] in 1 g
WHEY (UNII: 8617Z5FMF6) (WHEY - UNII:8617Z5FMF6)	WHEY	6 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBIC ACID (UNII: X045WJ989B)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
HARPAGOPHYTUM PROCUMBENS ROOT (UNII: 1OYM338E89)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
OREGANO (UNII: 0E5AT8T16U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43846-0065-1	18 14 g in 1 JUG; Type 0: Not a Combination Product	07/20/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/20/2016	

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0065) , api manufacture(43846-0065) , label(43846-0065) , pack(43846-0065)

Revised: 7/2016

Peaceful Mountain, Inc.