

**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, Whey Protein Concentrate (milk), Benzyl Alcohol, Ethylhexylglycerin, Tocopherol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer (Carbopol (Ultrez 21), Aloe Barbadensis Leaf Juice (Aloe Vera 10X Concentrate), Sodium Hydroxide (Solution), Edetate Disodium (EDTA), Arnica Montana, White Willow (bark), Witch Hazel (bark), Ascorbic Acid, Devil's Claw (root), Peppermint

(leaf).

QUESTIONS:

Dist. by Peaceful Mountain, Inc.

Woodbine, IA 51579

888-303-3388

www.peacefulmountain.com

PACKAGE LABEL DISPLAY:

arnica plus

peaceful mountain

THE HEIGHT OF HEALTH

homeopathic gel

paraben-free

formulated in

boulder, co

Net wt. 2 oz. (57 g)



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patent pending

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Arnica Montana 6x, 12x, Hamamelis Virginia 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.

Inactive Ingredients:

Extract Blend (Purified Water, Arnica [*Arnica montana*] Flower, White Willow [*Salix alba*] Bark, Witch Hazel [*Hamamelis virginiana*] Bark, Ascorbic Acid, Devil's Claw [*Harpagophytum procumbens*] Root, Peppermint [*Mentha piperita*] Leaf), Purified Water, Whey Protein Concentrate (milk), Benzyl Alcohol (and) Ethyl-hexylglycerin (and) Tocopherol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Sodium Hydroxide and Disodium EDTA

unscented • non-greasy • no petroleum • no animal testing

peaceful mountain®
THE HEIGHT OF HEALTH®

homeopathic gel

paraben-free



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boulder, co

Net wt. 2 oz. (57 g)

ARNICA PLUS

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0069
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 ROOT BARK/STEM BARK (UNII: T7S323PKJS) (HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	HAMAMELIS VIRGINIANA ROOT BARK/STEM 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: 059QF0K00R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
HAMAMELIS VIRGINIANA BARK (UNII: IH3063S9MY)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
HARPAGOPHYTUM PROCUMBENS ROOT (UNII: 1OYM338E89)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43846-0069-1	57 g in 1 TUBE; Type 0: Not a Combination Product	02/09/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		02/09/2018	

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0069) , api manufacture(43846-0069) , label(43846-0069) , pack(43846-0069)

