

ARNICA PLUS- arnica montana, hamamelis virginiana, rhus tox 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.

INDICATIONS:

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

**These statements are based upon traditional homeopathic practice. 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 • Condition 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, Grapeseed (Seed) Carrier Oil, Whey Protein Concentrate, Lecithin (Soy) (Liquid)Sodium Hydroxide (Solution), Phenoxyethanol, Caprylyl Glycol, Sorbic Acid, Acrylates/C10-30 Alkyl Acrylate Crosspolymer (Carbopol (Ultrez 21), Arnica (flower), Aloe Barbadosensis Leaf Juice, White Willow (bark), Witch Hazel (bark), Ascorbic Acid, Devil's Claw (root), Polysorbate 20, Tocopherol [Vitamin E Oil], Peppermint (leaf), Edetate Disodium (EDTA), Natural plant extract

(Origanox WS), Potassium Sorbate.

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

formulated in

boulder, co

Net wt. 2 oz. (57g)



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patent pending

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Directions:

Apply at least 3 times daily over the affected area.

Inactive Ingredients:

Purified Water, Vitis Vinifera (Grape) Seed Oil, Whey Protein Concentrate (milk), Lecithin (soy), Phenoxyethanol & 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

peaceful mountain®
 THE HEIGHT OF HEALTH®

homeopathic gel

paraben-free



formulated in
 boulder, co

Net wt. 2 oz. (57 g)

ARNICA PLUS

arnica montana, hamamelis virginiana, rhus tox gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0060
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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
WHEY (UNII: 8617Z5FMF6)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
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)	
HAMAMELIS VIRGINIANA BARK (UNII: IH3063S9MY)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
HARPAGOPHYTUM PROCUMBENS ROOT (UNII: 1OYM338E89)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MENTHA PIPERITA (UNII: 79M2M2UDA9)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
OREGANO (UNII: 0E5AT8T16U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43846-0060-1	57 g in 1 TUBE; Type 0: Not a Combination Product	05/09/2016	08/22/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		05/09/2016	

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0060) , api manufacture(43846-0060) , label(43846-0060) , pack(43846-0060)

Revised: 9/2016

Peaceful Mountain, Inc.