

ARNICA PLUS- arnica montana, hamamelis virginiana, rhus toxicodendron 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 Toxicodendron 6X,12X.

INDICATIONS

For temporary relief of 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 breastfeeding, 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.

DIRECTIONS

Apply at least 3 times daily over the affected area.

INACTIVE INGREDIENTS

Aloe Vera 10X Concentrate, Arnica (Flower) Arnica Montana, Carbomer (ULTREZ 21), Harpagophytum Procumbens (root), Edetate Disodium (EDTA), Origanox WS, PEG-33, PEG-8 Dimethicone, PEG-14 (Silsense, Copolyol 1 Silicone), Mentha Piperita (leaf), Phenoxyethanol and Caprylyl Glycol, Sorbic Acid (Optiphen Plus), Potassium Sorbate, Purified Water, Sodium Hydroxide (Solution), Ascorbic Acid, Vitamin E Oil (derived from Soy Bean), Salix Alba (bark), Hamamelis Virginiana.

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.

INDICATIONS AND USAGE

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QUESTIONS

Dist. by Peaceful Mountain, Inc.

Woodbine, IA 51579

888-303-3388

www.peacefulmountain.com

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: Aloe Vera Concentrate, Arnica Flower, Carbomer, Devil's Claw Root, Edetate Disodium, Natural Plant Extract, PEG-33 & PEG-8 Dimethicone & PEG-14, Peppermint Leaf, Phenoxyethanol & Caprylyl Glycol & Sorbic Acid, Potassium Sorbate, Purified Water, Sodium Hydroxide, Vitamin C, Vitamin E (soy), White Willow Bark and Witch Hazel Bark.

unscented · non-greasy
no petroleum · no animal testing

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patent pending

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Lot: G7691

ARNICA PLUS

arnica montana, hamamelis virginiana, rhus toxicodendron gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0026
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

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
HARPAGOPHYTUM PROCUMBENS ROOT (UNII: 1OYM338E89)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ORIGANUM VULGARE SUBSP. HIRTUM FLOWER (UNII: 3799SP11NY)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
POLYETHYLENE GLYCOL 700 (UNII: 762678AC5R)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBIC ACID (UNII: X045WJ989B)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0K00R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
SALIX ALBA BARK (UNII: 205MXS71H7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43846-0026-1	18 14 g in 1 JUG; Type 0: Not a Combination Product	10/11/2012	04/10/2019

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/11/2012	04/10/2019

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
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Apotheca
Company

844330915

manufacture(43846-0026) , api manufacture(43846-0026) , label(43846-0026) ,
pack(43846-0026)

Revised: 9/2016

Peaceful Mountain, Inc.