

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,

PURPOSE

For temporary relief of minor symptoms of sore, overexerted muscles.

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.

DIRECTIONS

Apply at least 3 times daily over the affected area.

INACTIVE INGREDIENTS

Aloe Vera 10X Concentrate, Arnica (flower) Arnica Montana, Carbomer (Ultrez21), Devil's Claw (root) Harpagophytum Procumbens, Edetat Disodium (EDTA), Natural Plant Extract (Origanox WS), PEG-33, PEG-8 Dimethicone, PEG-14, Peppermint (leaf) Mentha Piperita, Phenoxyethanol and Caprylyl Glycol and Sorbic Acid (Optiphen Plus), Potassium Sorbate, Purified Water, Sodium Hydroxide Solution, Vitamin C (Powder) Ascorbic Acid, Vitamin E Oil (derived from Soy Bean), White Willow (bark) Salix Alba, Witch Hazel (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

For temporary relief of minor symptoms of sore, overexerted muscles.

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

formulated in boulder, co

Net wt. 0.25 oz. (7 g)



ARNICA PLUS

arnica montana, hamamelis virginiana, rhus toxicodendron, gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0016
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
HARPAGOPHYTUM PROCUMBENS ROOT (UNII: 1OYM338E89)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ORIGANUM VULGARE SUBSP. HIRTUM FLOWER (UNII: 3799SP11NY)	

POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
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: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
HAMAMELIS VIRGINIANA BARK (UNII: IH3063S9MY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43846-0016-1	7 g in 1 PACKET; Type 0: Not a Combination Product	09/19/2012	08/20/2019

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		09/19/2012	

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0016) , api manufacture(43846-0016) , label(43846-0016) , pack(43846-0016)