

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:

0.17% of Arnica Montana 6X, 12X, Hamamelis Virginiana 6X, 12X, Rhus Tox 6X, 12X

INDICATIONS:

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

**Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

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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FDA evaluated.

INACTIVE INGREDIENTS:

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, Acrylates/C10-30 Alkyl acrylate Crosspolymer, Alkyl Acrylate Crosspolymer, Aloe Vera Leaf Juice, Phenoxyethanol, Caprylyl Glycol, Sorbic Acid, Peg-33, Peg-8 Dimethicone, Peg-14, Sodium Hydroxide, Tocopherols (soy), Disodium EDTA, Natural Plant Extract, Potassium Sorbate, Sodium Benzoate, Ethanol, Citric Acid.

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

Net wt. 2 oz. (57 g)



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patent pending

arnica plus®

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Active Ingredients (in gel):
0.17% of Arnica Montana 6x, 12x, Hamamelis Virginiana 6x, 12x, Rhus Tox 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, Phenoxyethanol (and) Caprylyl Glycol (and) Sorbic Acid, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, PEG-33 (and) Peg-8 Dimethicone (and) PEG-14, Aloe Barbadosensis Leaf Juice, Sodium Hydroxide, Tocopherols (soy), Disodium EDTA, 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:43846-0075
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARNICA MONTANA WHOLE (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA WHOLE	6 [hp_X] in 1 g
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS)	HAMAMELIS VIRGINIANA	6 [hp_X]

(HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	ROOT BARK/STEM BARK	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)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBIC ACID (UNII: X045WJ989B)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A)	
PEG-8 DIMETHICONE (UNII: GIA7T7640D)	
POLYETHYLENE GLYCOL 700 (UNII: 762678AC5R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
OREGANO (UNII: 0E5AT8T16U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
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)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALCOHOL (UNII: 3K9958V90M)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43846-0075-1	57 g in 1 TUBE; Type 0: Not a Combination Product	11/14/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/14/2018	

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0075) , api manufacture(43846-0075) , label(43846-0075) , pack(43846-0075)

Revised: 8/2023

Peaceful Mountain, Inc.