

JOINT AND TENDON RESCUE- bryonia (alba), ruta graveolens, bellis perennis, capsicum annuum, ledum palustre, symphytum officinale, colchicum autumnale, rhododendron chrysanthum, argentum metallicum 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:

(in gel): 0.11% of Argentum Metallicum 30X, Bellis Perennis 6X, Bryonia (Alba) 3X, Capsicum Annuum 6X, Colchicum Autumnale 12X, Ledum Palustre 6X, Rhododendron Chrysanthum 12X, Ruta Graveolens 3X, Symphytum Officinale 6X

INDICATIONS:

May temporarily relieve minor symptoms of joint pain and inflammation and tendon and soft tissue discomfort.**

**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.

Children under 12 years of age: Consult a doctor.

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INACTIVE INGREDIENTS:

Purified Water, Phenoxyethanol (and) Caprylyl Glycol (and) Sorbic Acid, Sodium Hydroxide (Solution), Acrylates/C10-30 Alkyl Acrylate Crosspolymer (Carbopol (Ultrez 21), PEG-33 (and) PEG-8 Dimethicone (and) PEG-14, Aloe Barbadensis Leaf Juice (Aloe Vera 10X Concentrate), Tocopherols [Vitamin E Oil] (derived from Soy Bean), Edetate Disodium (EDTA), Potassium Sorbate, Arnica (flower), Comfrey (leaf), White Willow (bark), Celery (seed), Devil's Claw (root), Feverfew (leaf), Poke (root), Ascorbic Acid, Turmeric (Root).

QUESTIONS:

Dist. by Peaceful Mountain, Inc.

Woodbine, IA 51579

888-303-3388

www.peacefulmountain.com

PACKAGE LABEL DISPLAY:

joint and tendon rescue

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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Active Ingredients (in gel):

0.11% of Arg Met 30x, Bellis 6x, Bryonia 3x, Capsicum 6x, Colchicum 12x, Ledum 6x, Rhododendron 12x, Ruta 3x, Symphytum 6x

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Directions:

Apply at least 3 times daily over the affected area. Children under 12 years of age: Consult a doctor.

Inactive Ingredients:

Extract Blend (Purified Water, Arnica [*Arnica montana*] Flower, Comfrey [*Symphytum officinale*] Leaf, White Willow [*Salix alba*] Bark, Celery [*Apium graveolens*] Seed, Devil's Claw [*Harpagophytum procumbens*] Root, Feverfew [*Tanacetum parthenium*] Leaf, Poke [*Phytolacca americana*] Root, Ascorbic Acid, Turmeric [*Curcuma longa*] Root), 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 Barbadensis Leaf Juice, Sodium Hydroxide, Tocopherols (soy), Disodium EDTA, Natural Plant Extract and Potassium Sorbate

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

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JOINT AND TENDON RESCUE

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0077
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	3 [hp_X] in 1 g
RUTA GRAVEOLENS FLOWERING TOP (UNII: N94C2U587S) (RUTA GRAVEOLENS FLOWERING TOP - UNII:N94C2U587S)	RUTA GRAVEOLENS FLOWERING TOP	3 [hp_X] in 1 g
BELLIS PERENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	6 [hp_X] in 1 g
CAPSICUM (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)	CAPSICUM	6 [hp_X] in 1 g
LEDUM PALUSTRE TWIG (UNII: 877L01IZ0P) (LEDUM PALUSTRE TWIG - UNII:877L01IZ0P)	LEDUM PALUSTRE TWIG	6 [hp_X] in 1 g
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	6 [hp_X] in 1 g
WHEY (UNII: 8617Z5FMF6) (WHEY - UNII:8617Z5FMF6)	WHEY	12 [hp_X] in 1 g
COLCHICUM AUTUMNALE BULB (UNII: 993QHL78E6) (COLCHICUM AUTUMNALE BULB - UNII:993QHL78E6)	COLCHICUM AUTUMNALE BULB	12 [hp_X] in 1 g
RHODO DENDRON AUREUM LEAF (UNII: IV92NQJ73U) (RHODO DENDRON AUREUM LEAF - UNII:IV92NQJ73U)	RHODO DENDRON AUREUM LEAF	30 [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)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
POLYETHYLENE GLYCOL 700 (UNII: 762678AC5R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
OREGANO (UNII: 0E5AT8T16U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
COMFREY LEAF (UNII: DG4F8T839X)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
CELERY SEED (UNII: 1G1EAA320L)	
HARPAGOPHYTUM PROCUMBENS ROOT (UNII: 1OYM338E89)	
FEVERFEW (UNII: Z64FK7P217)	
PHYTOLACCA AMERICANA ROOT (UNII: 11E6VI8VEG)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
TURMERIC (UNII: 856YO1Z64F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43846-0077-1	57 g in 1 TUBE; Type 0: Not a Combination Product	12/12/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/12/2018	

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0077) , api manufacture(43846-0077) , label(43846-0077) , pack(43846-0077)

Revised: 12/2018

Peaceful Mountain, Inc.