

BACK, NECK AND SCIATIC RESCUE- *phytolacca decandra*, *gnaphalium polycephalum*, *hypericum perforatum*, *colocynthis*, *gelsemium sempervirens*, *guaiaicum*, *ledum palustre*, whey protein, *conium maculatum* 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:

Phytolacca Decandra 1X, Gnaphalium Polycephalum 3X, Hypericum Perforatum 3X, Colocynthis 6X, Gelsemium Sempervirens 6X, Guaiacum 6X, Ledum Palustre 6X, Whey Protein 6X, Conium Maculatum 30X

INDICATIONS:

May temporarily relieve minor symptoms of back and neck discomfort and sharp pain along the sciatic nerve, lower back and down the back of the legs.**

**These statements are based upon traditional homeopathic principles. 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 • Conditions worsens Symptoms last more than 7 days

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, Vitis Vinifera (Grape) Seed Oil, Whey Protein, Lecithin (Soy), Phenoxyethanol, Caprylyl Glycol, Sorbic Acid, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadosis Leaf, Arnica Montana (Flower), Comfrey (Leaf), Jamaica Dogwood (Bark), Phytolacca Americana (Root), Hypericum Perforatum (Aerial Parts), White Willow (Bark), Achillea Millefolium (Flower), Polysorbate 20, Lavandula Angustifolia (Buds), Sodium Hydroxide (Solution), Ascorbic Acid (Vitamin C), Tocopherols (Derived From Soy Bean), Edetate Disodium (EDTA), Oregano, Potassium Sorbate

QUESTIONS:

Dist. by Peaceful Mountain, Inc.
Woodbine, IA 51579 888-303-3388
www.peacefulmountain.com

PACKAGE LABEL DISPLAY:

peaceful mountain

THE HEIGHT OF HEALTH

homeopathic gel

back, neck and sciatic rescue

formulated in boulder, co

Net wt. 0.25 oz. (7 g)

peaceful mountain.
THE HEIGHT OF HEALTH[®]

homeopathic gel

back, neck and sciatic rescue™

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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.

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, Aloe Barbadosis Leaf Juice, Achillea Millefolium (Yarrow) Flower Extract, Arnica Montana (Aerial) Flower Extract, Hypericum Perforatum (St. John's Wort) Aerial Parts Extract, Phytolacca Americana (Poke) Root Extract, Piculida Pictipula (Jamaica Dogwood) Bark Extract, Salix Alba (White Willow) Bark Extract, Sympterygium Ditchiana (Comfrey) Leaf Extract, Polysorbate 20, Lavandula Angustifolia (Lavender) Buds Extract, Sodium Hydroxide, Ascorbic Acid, Tocopherols (Soy), Edetate Disodium, Natural Plant Extract and Potassium Sorbate.

8 18692-00952-18

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BACK, NECK AND SCIATIC RESCUE

phytolacca decandra, gnaphalium polycephalum, hypericum perforatum, colocynthis, gelsemium sempervirens, guaiacum, ledum palustre, whey protein, conium maculatum gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0066
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHYTOLACCA AMERICANA ROOT (UNII: 11E6V18VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6V18VEG)	PHYTOLACCA AMERICANA ROOT	1 [hp_X] in 1 g
PSEUDOGNAPHALIUM OBTUSIFOLIUM (UNII: 36XQ854NWW) (PSEUDOGNAPHALIUM OBTUSIFOLIUM - UNII:36XQ854NWW)	PSEUDOGNAPHALIUM OBTUSIFOLIUM	3 [hp_X] in 1 g
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	3 [hp_X] in 1 g

CITRULLUS COLOCYNTHIS FRUIT PULP (UNII: 23H32AOH17) (CITRULLUS COLOCYNTHIS FRUIT PULP - UNII:23H32AOH17)	CITRULLUS COLOCYNTHIS FRUIT PULP	6 [hp_X] in 1 g
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	6 [hp_X] in 1 g
GUAIAACUM OFFICINALE RESIN (UNII: N0K2Z502R6) (GUAIAACUM OFFICINALE RESIN - UNII:N0K2Z502R6)	GUAIAACUM OFFICINALE RESIN	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
WHEY (UNII: 8617Z5FMF6) (WHEY - UNII:8617Z5FMF6)	WHEY	6 [hp_X] in 1 g
CONIUM MACULATUM FLOWERING TOP (UNII: Q28R5GF371) (CONIUM MACULATUM FLOWERING TOP - UNII:Q28R5GF371)	CONIUM MACULATUM FLOWERING TOP	30 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBIC ACID (UNII: X045WJ989B)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
COMFREY LEAF (UNII: DG4F8T839X)	
PISCIDIA PISCIPULA ROOT BARK (UNII: 58JV0P12FY)	
ST. JOHN'S WORT (UNII: UFH8805FKA)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
TOCOPHEROL (UNII: R0ZB2556P8)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
OREGANO (UNII: 0E5AT8T16U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43846-0066-1	7 g in 1 PACKET; Type 0: Not a Combination Product	09/14/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		09/14/2016	

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0066) , api manufacture(43846-0066) , label(43846-0066) , pack(43846-0066)

Revised: 9/2016

Peaceful Mountain, Inc.