

BACK AND NECK RESCUE- hypericum perforatum, phytolacca decandra, guaiacum, ledum palustre, 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

Hypericum Perforatum 3X, Phytolacca Decandra 3X, Guaiacum 6X, Ledum Palustre 6X, Conium Maculatum 30X

INDICATIONS

For temporary relief of minor symptoms of back and neck discomfort.

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. Consult a physician for use in children under 12 years of age.

INACTIVE INGREDIENTS

Aloe Vera, Arnica Montana (flower), Carbomer (Ultrez 21), Comfrey (leaf), Edetate Disodium, Lavender (buds), Origanox WS, PEG-33, PEG-8 Dimethicone, PEG-14, Phenoxyethanol, Capryly Glycol, Sorbic Acid, Potassium Sorbate, Water, Sodium Hydroxide Solution, Hypericum Perforatum, Ascorbic Acid, Vitamin E Oil, Salix Alba (bark), Achillea Millefolium (flower)

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 back and neck discomfort.

QUESTIONS

Dist. by Peaceful Mountain, Inc. Woodbine, IA 51579

888-303-3388 www.peacefulmountain.com

peaceful mountain

THE HEIGHT OF HEALTH

back and neck rescue

homeopathic gel

paraben free

unscented non greasy no petroleum no menthol no animal testing

formulated in boulder, co

Net wt. 2 oz (57 g)

Indications: For the temporary relief of minor symptoms of back and neck discomfort.**

** These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

Active Ingredients: Hypericum Perforatum 3x, Phytolacca Decandra 3x, Guaiacum 6x, Ledum Palustre 6x, Conium Maculatum 30x

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Directions: Apply at least 3 times daily over the affected area. Consult a physician for use in children under 12 years of age.

Inactive Ingredients: Aloe Vera Concentrate, Arnica Flower, Carbomer, Comfrey Leaf, Edetate Disodium, Lavender Buds, Natural Plant Extract, PEG-33 & PEG-8 Dimethicone & PEG-14, Phenoxyethanol & Caprylyl Glycol & Sorbic Acid, Potassium Sorbate, Purified Water, Sodium Hydroxide, St. John's Wort Aerial Parts, Vitamin C, Vitamin E (soy), White Willow Bark and Yarrow Flower

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BACK AND NECK RESCUE

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	3 [hp_X] in 1 g

PHYTOLACCA AMERICANA ROOT (UNII: 11E6V18VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6V18VEG)	PHYTOLACCA AMERICANA ROOT	3 [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: 877L01Z0P) (LEDUM PALUSTRE TWIG - UNII:877L01Z0P)	LEDUM PALUSTRE TWIG	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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
COMFREY LEAF (UNII: DG4F8T839X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	
OREGANO (UNII: 0E5AT8T16U)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
POLYETHYLENE GLYCOL 700 (UNII: 762678AC5R)	
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)	
ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43846-0009-1	57 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/19/2013	

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0009)

Revised: 5/2013

Peaceful Mountain, Inc.