

HOT FLASH RESCUE- not applicable lotion
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:

Capsicum Annuum 3X, Pulsatilla (Vulgaris) 3X, Sanguinaria Candensis 3X

INDICATIONS:

For temporary relief of menopausal disorders including flushes of heat, heavy menses with pain in left ovarian region and burning palms and soles.**

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

WARNINGS:

For external use only.

If pregnant, breast-feeding, taking birth control or on hormone replacement therapy, 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.

This product is not intended as an alternative hormone therapy.□

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 daily to neck, chest, abdomen, inner arms or inner thighs. Begin with two metered pumps morning and evening: adjust dose for your personal needs and comfort.

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INACTIVE INGREDIENTS:

Aloe Vera Concentrate, Avocado Oil, Black Cohosh Root, Carbomer (Ultrez 21), Chaste Tree Fruit, Edetate Disodium, Kukui Nut Oil, Lavender Buds, Macadamia Nut Oil, Natural Plant Extract, Olive Seed Oil, PEG-33, PEG-8 Dimethicone, PEG-14, Phenoxyethanol, Caprylyl Glycol, Sorbic Acid, Polysorbate 20, Potassium Sorbate, Purified Water, Rose Hips Seed Oil, Sage Leaf, Sodium Hydroxide, St. John's Wort Aerial Parts, Vitamin C, Vitamin E (Soy), Wild Yam Root

QUESTIONS:

Dist. by Peaceful Mountain, Inc.
 Woodbine, IA 51579
 888.303.3388
 www.peacefulmountain.com

PACKAGE DISPLAY LABEL:

peaceful mountain
 THE HEIGHT OF HEALTH
hot flash rescue
 homeopathic lotion
 paraben-free
 organic and wild-crafted herbs
 formulated in boulder, co
Net wt. 3.5 oz. (100 g)



HOT FLASH RESCUE			
not applicable lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0036

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSICUM (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)	CAPSICUM	3 [hp_X] in 1 g
PULSATILLA VULGARIS (UNII: I76KB35JEV) (PULSATILLA VULGARIS - UNII:I76KB35JEV)	PULSATILLA VULGARIS	3 [hp_X] in 1 g
SANGUINARIA CANADENSIS ROOT (UNII: N9288CD508) (SANGUINARIA CANADENSIS ROOT - UNII:N9288CD508)	SANGUINARIA CANADENSIS ROOT	3 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
BLACK COHOSH (UNII: K73E24S6X9)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CHASTE TREE (UNII: 433OSF3U8A)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
KUKUI NUT OIL (UNII: TP11QR7B8R)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AHIRAF4M)	
MACADAMIA OIL (UNII: 515610SU8C)	
OREGANO (UNII: 0E5AT8T16U)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
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)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
ROSA CANINA SEED (UNII: 4503R1M9UT)	
SAGE (UNII: 065C5D077J)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
DIOSCOREA VILLOSA ROOT (UNII: IWY3IWX2G8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43846-0036-1	100 g in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/01/2014	

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0036) , api manufacture(43846-0036) , label(43846-0036) , pack(43846-0036)

Revised: 10/2014

Peaceful Mountain, Inc.