

HOT FLASH RESCUE- capsicum annuum, pulsatilla pratensis), sanguinaria canadensis spray
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 each spray): 0.33% of Capsicum Annuum 3X, Pulsatilla (Pratensis) 4X, Sanguinaria Canadensis 3X.

INDICATIONS:

May temporarily relieve menopausal disorders including flushes of heat, heavy menses with pain in left ovarian region and burning palms and soles. **

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

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. Use as needed.

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INACTIVE INGREDIENTS:

Water, Wild Yam (Dioscorea Villosa) Root, Black Cohosh (Actaea Racemosa) Root, Chaste Tree (Vitex agnus-castus) Fruit, Lavender (Lavandula angustifolia) Buds, Sage (Salvia officinalis) Leaf, Ascorbic Acid, St John's Wort (Hypericum Perforatum) Aerial Parts, Purified Water, Phenoxyethanol, Caprylyl Glycol, Sorbic Acid, Aloe Barbadensis Leaf Juice, Tocopherols (soy), Natural Plant Extract, Potassium Sorbate, Ethanol, Citric Acid.

QUESTIONS:

Dist. by Peaceful Mountain, Inc.

Woodbine, IA 51579

888-303-3388

www.peacefulmountain.com

no animal testing

PACKAGE LABEL DISPLAY:

peaceful mountain

THE HEIGHT OF HEALTH

hot flash rescue

homeopathic spray

soothing mist

2 fl. oz. (59 ml)

Active Ingredients (in each spray): 0.33% of Capsicum Annuum 3x, Pulsatilla 4x, Sanguinaria Canadensis 3x
 Inactive Ingredients: Water/Wild Yam (*Dioscorea villosa*) Root/Black Cohosh (*Actaea racemosa*) Root/Chaste Tree (*Vitex agnus-castus*) Fruit/English Lavender (*Lavandula angustifolia*) Buds/Sage (*Salvia officinalis*) Leaf/Ascorbic Acid/St. John's Wort (*Hypericum perforatum*) Leaf, Flower, Stem Extract, Water, Phenoxyethanol, Caprylyl Glycol, Sorbic Acid, Aloe Vera Leaf Juice, Natural Plant Extract, Tocopherols (soy), Potassium Sorbate, Sodium Benzoate, Ethanol and Citric Acid.

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Lot:

HOT FLASH RESCUE

capsicum annuum, pulsatilla pratensis), sanguinaria canadensis spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0081
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 mL
PULSATILLA PRATENSIS WHOLE (UNII: 8E272251DI) (PULSATILLA PRATENSIS WHOLE - UNII:8E272251DI)	PULSATILLA PRATENSIS WHOLE	4 [hp_X] in 1 mL
SANGUINARIA CANADENSIS ROOT (UNII: N9288CD508) (SANGUINARIA CANADENSIS ROOT - UNII:N9288CD508)	SANGUINARIA CANADENSIS ROOT	3 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBIC ACID (UNII: X045WJ989B)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
OREGANO (UNII: 0E5AT8T16U)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
DIOSCOREA VILLOSA TUBER (UNII: IWY3IWX2G8)	
BLACK COHOSH (UNII: K73E24S6X9)	
CHASTE TREE FRUIT (UNII: 433OSF3U8A)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	

SAGE (UNII: 065C5D077J)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)	
ALCOHOL (UNII: 3K9958V90M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43846-0081-1	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/18/2021	

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0081) , api manufacture(43846-0081) , label(43846-0081) , pack(43846-0081)

Revised: 3/2021

Peaceful Mountain, Inc.