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.

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.

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

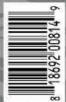
PACKAGE LABEL DISPLAY:

peaceful mountain

THE HEIGHT OF HEALTH
hot flash rescue
homeopathic spray
soothing mist

2 fl. oz. (59 ml)





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

no animal testing

Lot:



hot flash rescue

homeopathic spray

soothing mist

2 fl. oz. (59 mL)

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

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 Denot 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.

Directions: Apply daily to neck, chest, abdomen, inner arms or inner thighs. Use as needed.

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

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 3 [hp X] CAPSICUM (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG) **CAPSICUM** in 1 mL PULSATILLA PRATENSIS WHOLE (UNII: 8E272251DI) (PULSATILLA PRATENSIS **PULSATILLA PRATENSIS** 4 [hp X] WHOLE - UNII:8E272251DI) WHOLE in 1 mL SANGUINARIA CANADENSIS ROOT (UNII: N9288CD508) (SANGUINARIA SANGUINARIA 3 [hp X] CANADENSIS ROOT - UNII:N9288CD508) CANADENSIS ROOT 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)		
.ALPHATOCOPHEROL (UNII: H4N855PNZ1)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
DIOSCOREA VILLOSA TUBER (UNII: IWY3IWX2G8)		
BLACK COHOSH (UNII: K73E24S6X9)		
CHASTE TREE FRUIT (UNII: 4330SF3U8A)		
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)		

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

l	Packaging				
	#	Item Code	Item Code Package Description Marke		Marketing End Date
	1	NDC:43846- 0081-1	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/18/2021	03/11/2026

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/18/2021	03/11/2026

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: 6/2024 Peaceful Mountain, Inc.