

ECZEMA RESCUE- cabolicum acidum, fagopyrum esculentum, hydrastis canadensis, hydrocotyle asiatica, juglans regia, vinca minor 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:

CABOLICUM ACIDUM 30X, FAGOPYRUM ESCULENTUM 30X, HYDRASTIS CANADENSIS 30X, HYDROCOTYLE ASIATICA 30X, JUGLANS REGIA 30X, VINCA MINOR 30X

SUGGESTED USE:

Helps temporarily relieve minor symptoms of eczema such as irritated, red, burning, itching, dry, rough, scaly, chapped, cracked skin, rashes, urticaria (hives), eruptions, eczema, psoriasis, generally unhealthy skin.

WARNINGS:

For external use only.

Avoid contact with eyes.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

If pregnant or breast-feeding, ask a health professional before use.

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

SUGGESTED USE:

Helps temporarily relieve minor symptoms of eczema such as irritated, red, burning, itching, dry, rough, scaly, chapped, cracked skin, rashes, urticaria (hives), eruptions, eczema, psoriasis, generally unhealthy skin.

INACTIVE INGREDIENTS:

ALOE VERA 10X CONCENTRATE, ARNICA MONTANA (FLOWER), AVOCADO OIL, SANGUINARIA CANADENSIS (ROOT), CALENDULA OFFICINALIS (FLOWER), CARBOMER (ULTREZ 21), LARREA TRIDENTATA (LEAF), SYMPHYTUM OFFICINALE (LEAF), EDETATE DISODIUM (EDTA), KUKUI NUT OIL, MACADAMIA NUT OIL, NATURAL PLANT EXTRACT

(ORIGANOX WS), AZADIRACHTA INDICA (LEAF), OLIVE OIL, PEG-33, PEG-8 DIMETHICONE, PEG-14 (SILSENSE COPOLYOL-1 SILICONE), PHENOXYETHANOL, CAPRYLYL GLYCOL, SORBIC ACID (OPTIPHEN PLUS) PHYTOLACCA AMERICANA (BERRY), PHYTOLACCA AMERICANA (ROOT), POLYSORBATE 20 [TWEEN 20], POTASSIUM SORBATE, PURIFIED WATER, SODIUM HYDROXIDE (SOLUTION), HYPERICUM PERFORATUM (AERIAL PARTS), VITAMIN C (POWDER)[ASCORBIC ACID], VITAMIN E (DERIVED FROM SOY BEAN), SALIX ALBA (BARK)

QUESTIONS:

Dist. by:

Peaceful Mountain, Inc.

Woodbine, IA 51579

888-303-3388

www.peacefulmountain.com

PACKAGE LABEL DISPLAY:

Peaceful Mountain

Eczema Rescue

Homeopathic Lotion

Net wt. 4 lbs. (64 oz.) (1.8 kg)

Peaceful Mountain Eczema Rescue[®] Homeopathic Lotion

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dry, rough, scaly, chapped,
cracked skin, rashes, urticaria
(hives), eruptions, eczema,
psoriasis, generally unhealthy skin.

ACTIVE INGREDIENTS:

Carbolicum Acidum 30X, Fagopyrum Esculentum 30X,
Hydrastis Canadensis 30X, Hydrocotyle Asiatica 30X,
Juglans Regia 30X, Vinca Minor 30X.

INACTIVE INGREDIENTS:

Aloe Vera Concentrate, Arnica Flower, Avocado Oil,
Bloodroot Root, Calendula Flower, Carbomer, Chaparral
Leaf, Comfrey Leaf, Edetate Disodium, Kukui Nut Oil,
Macadamia Nut Oil, Natural Plant Extract, Neem Leaf,
Olive Oil, PEG-33 & PEG-8 Dimethicone & PEG-14,
Phenoxyethanol & Caprylyl Glycol & Sorbic Acid, Poke
Berry, Poke Root, Polysorbate 20, Potassium Sorbate,
Purified Water, Sodium Hydroxide, St. John's Wort
Aerial Parts, Vitamin C, Vitamin E (soy) and White
Willow Bark.

Net wt. 4 lbs. (64 oz.) (1.8 kg)

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LOT: XXXXXX

ECZEMA RESCUE

carbolicum acidum, fagopyrum esculentum, hydrastis canadensis, hydrocotyle asiatica, juglans regia, vinca minor
lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:43846-0019

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	30 [hp_X] in 1 g
FAGOPYRUM ESCULENTUM (UNII: B10M69172N) (FAGOPYRUM ESCULENTUM - UNII:B10M69172N)	FAGOPYRUM ESCULENTUM	30 [hp_X] in 1 g
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	30 [hp_X] in 1 g
CENTELLA ASIATICA (UNII: 7M867G6T1U) (CENTELLA ASIATICA - UNII:7M867G6T1U)	CENTELLA ASIATICA	30 [hp_X] in 1 g
JUGLANS REGIA LEAF (UNII: 85HKB87105) (JUGLANS REGIA LEAF - UNII:85HKB87105)	JUGLANS REGIA LEAF	30 [hp_X] in 1 g
JUGLANS REGIA FRUIT RIND, IMMATURE (UNII: ZPS7Q5U53K) (JUGLANS REGIA FRUIT RIND, IMMATURE - UNII:ZPS7Q5U53K)	JUGLANS REGIA FRUIT RIND, IMMATURE	30 [hp_X] in 1 g
VINCA MINOR (UNII: WGM46PQF02) (VINCA MINOR - UNII:WGM46PQF02)	VINCA MINOR	30 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
SANGUINARIA CANADENSIS ROOT (UNII: N9288CD508)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
LARREA TRIDENTATA TOP (UNII: PK0TXD049P)	
COMFREY LEAF (UNII: DG4F8T839X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
KUKUI NUT OIL (UNII: TP11QR7B8R)	
MACADAMIA OIL (UNII: 515610SU8C)	
OREGANO (UNII: 0E5AT8T16U)	
AZADIRACHTA INDICA LEAF (UNII: HKY915780T)	
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)	
PHYTOLACCA AMERICANA FRUIT (UNII: WE63661499)	
PHYTOLACCA AMERICANA ROOT (UNII: 11E6V18VEG)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

SALIX ALBA BARK (UNII: 205MXS71H7)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43846-0019-1	18 14 g in 1 JUG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/15/2014	

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0019) , api manufacture(43846-0019) , label(43846-0019) , pack(43846-0019)

Revised: 12/2014

Peaceful Mountain, Inc.