

CHAFE RESCUE- bryonia, arsenicum iodatum, baryta carbonica, alumina, calendula officinalis, sulphuricum acidum, symphytum officinale 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:

Bryonia (Alba) 1X, Arsenicum Iodatum 6X, Baryta Carbonica 8X, Alumina 12X, Calendula Officinalis 12X, Sulphuricum Acidum 12X, Symphytum Officinale 12X.

INDICATIONS:

For the temporary relief of discomfort from friction and chafing.**

**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 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 - Do not apply to broken or abraded skin.

☐ **Stop use and ask a doctor if** ☐ - Condition worsens - Symptoms last more than 7 days.

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 liberally before and after physical exercise. Consult a physician for use in children under 12 years of age.

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INACTIVE INGREDIENTS:

Allantoin, Aloe Vera Concentrate, Arnica Flower, Avocado oil, Calendula Flower, Carbomer, Comfrey Leaf, Edetate Disodium, Kukui Nut Oil, Lavender Buds, Macadamia Nut Oil, Natural Plant Extract, PEG-

33, PEG-8 Dimethicone, PEG-14, Phenoxyethanol, Caprylyl Glycol, Sorbic Acid, Polysorbate 20, Potassium Sorbate, Purified Water, Rose Hips Seed Oil, Sodium Hydroxide, Soy Bean Seed Oil, Vitamin C, Vitamin E (Soy), White Willow Bark

QUESTIONS:

Dist. by Peaceful Mountain, Inc.

Woodbine, IA 51579

888-303-3388

www.peacefulmountain.com

PACKAGE DISPLAY LABEL:

peaceful mountain

THE HEIGHT OF HEALTH

chafe rescue

homeopathic lotion

formulated in boulder, co

Net wt. 0.25 oz. (7 g)



CHAFE RESCUE

bryonia, arsenicum iodatum, baryta carbonica, alumina, calendula officinalis, sulphuricum acidum, symphytum officinale lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0037
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BRYONIA ALBA ROOT (UNII: T7J046 YI2B) (BRYONIA ALBA ROOT - UNII:T7J046 YI2B)	BRYONIA ALBA ROOT	1 [hp_X] in 1 g
ARSENIC TRIIODIDE (UNII: 3029988O2T) (ARSENIC CATION (3+) - UNII:C966 13F5AV)	ARSENIC CATION (3+)	6 [hp_X] in 1 g
BARIUM CARBONATE (UNII: 6P669D8HQ8) (BARIUM CATION - UNII:V645272HLN)	BARIUM CATION	8 [hp_X] in 1 g
ALUMINUM OXIDE (UNII: LM26 O6933) (ALUMINUM OXIDE - UNII:LM26 O6933)	ALUMINUM OXIDE	12 [hp_X] in 1 g

CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	12 [hp_X] in 1 g
SULFURIC ACID (UNII: O40UQP6WCF) (SULFURIC ACID - UNII:O40UQP6WCF)	SULFURIC ACID	12 [hp_X] in 1 g
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	12 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
COMFREY LEAF (UNII: DG4F8T839X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
KUKUI NUT OIL (UNII: TP11QR7B8R)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AHIRAF4M)	
MACADAMIA OIL (UNII: 515610SU8C)	
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)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0K00R)	
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SOYBEAN OIL (UNII: 241ATL177A)	
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:43846-0037-1	7 g in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/02/2014	

Labeler - Peaceful Mountain, Inc (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0037) , api manufacture(43846-0037) , label(43846-0037) , pack(43846-0037)

Revised: 1/2014

Peaceful Mountain, Inc