

**BITE, BUMP AND RASH RELIEF- apis mellifica, astacus fluviatilis, belladonna, calcarea carbonica, gelsemium sempervirens, mezereum, rhus tox gel
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 gel): 1.43% of Apis Mellifica 12X, Astacus Fluviatilis 15X, Belladonna 12X, Calcarea Carbonica 12X, Gelsemium Sempervirens 15X, Mezereum 12X, Rhus Tox 12X.

INDICATIONS:

May temporarily relieve itching, insect bites, poison ivy, rashes, eczema, hives, inflammation and irritated red skin.**

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

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.

Stop use and ask a doctor if • Conditions worsens • Symptoms last more than 7 days

Do not use if safety seal is broken or missing.

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 the affected area.

Children under 12 years of age: Consult a doctor.

INDICATIONS:

May temporarily relieve itching, insect bites, poison ivy, rashes, eczema, hives, inflammation and irritated red skin.**

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

INACTIVE INGREDIENTS:

Aloe Barbadensis Leaf Juice, Purified Water, Benzyl Alcohol (and) Ethylhexylglycerin (and) Tocopherol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Disodium EDTA, Sodium Hydroxide (Solution).

QUESTIONS:

Dist. by Peaceful Mountain, Inc.

Woodbine, IA 51579

888-303-3388

www.peacefulmountain.com

PACKAGE LABEL DISPLAY:

peaceful mountain

THE HEIGHT OF HEALTH

bite, bump and

rash relief

homeopathic

anti-itch gel

paraben-free

unscented • non-greasy

No menthol • no animal testing

Net wt. 2 oz. (57 g)

Indications: May temporarily relieve itching, insect bites, poison ivy, rashes, eczema, hives, inflammation and irritated red skin.**

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

Active Ingredients (in gel): 1.43% of Apis Mel 12x, Astacus 15x, Belladonna 12x, Calc Carb 12x, Gelsemium 15x, Mezereum 12x, Rhus Tox 12x

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** • An adverse reaction occurs • Condition worsens • Symptoms last more than 7 days. Do not use if safety seal is broken or missing.

Directions: Apply topically to affected area 4 to 6 times daily.

Inactive Ingredients: Aloe Barbadensis Leaf Juice, Purified Water, Benzyl Alcohol (and) Ethylhexylglycerin (and) Tocopherol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Disodium EDTA, Sodium Hydroxide



Lot: XXXXXX

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BITE, BUMP AND RASH RELIEF

apis mellifica, astacus fluviatilis, belladonna, calcarea carbonica, gelsemium sempervirens, mezereum, rhus tox gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0079
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
APIS MELLIFERA (UNII: 7S82P3R43Z) (APIS MELLIFERA - UNII:7S82P3R43Z)	APIS MELLIFERA	12 [hp_X] in 1 g
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	12 [hp_X] in 1 g
OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	12 [hp_X] in 1 g
DAPHNE MEZEREUM BARK (UNII: X2N6E405GV) (DAPHNE MEZEREUM BARK - UNII:X2N6E405GV)	DAPHNE MEZEREUM BARK	12 [hp_X] in 1 g
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	12 [hp_X] in 1 g
ASTACUS ASTACUS (UNII: V0551986XQ) (ASTACUS ASTACUS - UNII:V0551986XQ)	ASTACUS ASTACUS	15 [hp_X] in 1 g
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	15 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43846-0079-1	57 g in 1 TUBE; Type 0: Not a Combination Product	01/10/2019	04/02/2026

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/10/2019	04/02/2026

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0079) , api manufacture(43846-0079) , label(43846-0079) , pack(43846-0079)

Revised: 5/2025

Peaceful Mountain, Inc.