

**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.*

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**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: 059QF0K00R)	
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	

## Marketing Information

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

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**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: 1/2019

Peaceful Mountain, Inc.