

ACNE RESCUE- borax, carbo vegetabilis, carboneum sulphuratum, causticum, natrum muriaticum, silicea 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:

Borax 30X, Carbo Vegetabilis 12X, Carboneum Sulphuratum 12X, Causticum 12X, Natrum Muriaticum 30X, Silicea 30X.

USES:

Temporarily relieves symptoms associated with acne: • pimples • redness • itching • inflammation.**

**These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

WARNINGS:

For external use only.

☐ **When using this product**

☐ • Do not get into eyes

Stop use and ask a doctor if

• Condition worsens

• Symptoms last more than 7 days

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

INDICATIONS:

Temporarily relieves symptoms associated with acne: • pimples • redness • itching • inflammation.**

**These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

INACTIVE INGREDIENTS:

Aloe Barbadensis Leaf Juice (Aloe Vera 10x Concentrate), Arnica Montana (Flower), Carbomer (Ultrez 21), Larrea Tridentata (Leaf), Symphytum Officinale (Leaf), Edetate Disodium (EDTA), Lavandula Angustifolia (Buds), Melissa Officinalis (Leaf), Natural Plant Extract (Origanox WS), [PEG-33, PEG-8 Dimethicone, PEG-14 (Silsense Copolyol-1 Silicone)], [Phenoxyethanol, Caprylyl Glycol, Sorbic Acid (Optiphen-Plus)], Phytolacca Americana (Berry), Phytolacca Americana (Root), Potassium Sorbate, Purified Water, Sodium Hydroxide (Solution), Hypericum Perforatum (Aerial Parts), Vitamin C (Powder) [Ascorbic Acid], Tocopherol [Vitamin E Oil](Derived From Soy Bean), Salix Alba (Bark), Achillea Millefolium (Flower).

QUESTIONS:

888-303-3388 Mon-Fri 8 a.m.-5 p.m. CST

Dist. by Peaceful Mountain, Inc., Woodbine, IA 51579 | www.peacefulmountain.com

PACKAGE LABEL DISPLAY:

acne

rescue

homeopathic

gel

Fast acting, natural

formula providing

temporary relief from

unsightly skin

conditions such as

acne and rosacea.

peaceful mountain

THE HEIGHT OF HEALTH

Net wt. 0.5 oz. (14 g)

Directions: Apply twice daily over affected area. For external use only. Consult a physician for use in children under 12 years of age.

Uses: Temporarily relieves symptoms associated with acne: • pimples • redness • itching • inflammation.**

**These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

Dist. by Peaceful Mountain, Inc. Woodbine, IA 51579 • 888-303-3384 • www.peacefulmountain.com

peaceful mountain®
THE HEIGHT OF HEALTH®

acne rescue™

Net wt. 0.5 oz. (14 g)



Drugs facts (continued)

Uses Temporarily relieves symptoms associated with acne: • pimples • redness • itching • inflammation.**

**These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

Warnings

For external use only

Stop use and ask a doctor if

When using this product

• Do not get into eyes

- Condition worsens
- Symptoms last more than 7 days

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. ▼

Directions Apply twice daily over affected area. Consult a physician for use in children under 12 years of age.

Inactive Ingredients Aloe Vera Concentrate, Arnica Flower, Carbomer, Chaparral Leaf, Comfrey Leaf, Edetate Disodium, Lavender Buds, Lemon Balm Leaf, Natural Plant Extract, PEG-33 & PEG-8 Dimethicone & PEG-14, Phenoxyethanol & Caprylyl Glycol & Sorbic Acid, Poke Berry, Poke Root, Potassium Sorbate, Purified Water, Sodium Hydroxide, St. John's Wort Aerial Parts, Vitamin C, Vitamin E (soy), White Willow Bark and Yarrow Flower.

Questions? 888-303-3388 Mon–Fri 8 a.m.–5 p.m. CST

Dist. by Peaceful Mountain, Inc., Woodbine, IA 51579 | www.peacefulmountain.com

acne
rescue™

homeopathic
gel

Fast acting, natural
formula providing
temporary relief from
unslightly skin
conditions such as
acne and rosacea.

peaceful mountain.
THE HEIGHT OF HEALTH®

Net wt. 0.5 oz. (14 g)

Drug Facts

Active Ingredients

Purpose: Relief from

Borax 30X	Unhealthy skin; slight injuries become suppurative; wilted wrinkled skin
Carbo Vegetabilis 12X	Ulcers with offensive discharge
Carboneum Sulphuratum 12X	Chronic skin diseases; red elevated eruptions on face
Causticum 12X	Acne and rosacea
Natrium Murialicum 30X	Dry, chapped, or greasy oily skin; herpetic eruptions
Silicea 30X	Waxy, unhealthy skin; suppurative injuries; acne



Directions: Apply twice daily over affected area. For external use only. Consult a physician for use in children under 12 years of age.

Uses: Temporarily relieves symptoms associated with acne: • pimples • redness • itching • inflammation.**

**These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

Dist. by Peaceful Mountain, Inc. Woodbine, IA 51579 • 888-303-3384 • www.peacefulmountain.com

peaceful mountain.
THE HEIGHT OF HEALTH®

acne rescue™



Net wt. 0.5 oz. (14 g)

ACNE RESCUE

borax, carbo vegetabilis, carboneum sulphuratum, causticum, natrum muriaticum, silicea gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0039
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM BORATE (UNII: 91MBZ8H3QO) (BORATE ION - UNII:440AE30D22)	SODIUM BORATE	30 [hp_X] in 1 g
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10) (ACTIVATED CHARCOAL - UNII:2P3VWU3H10)	ACTIVATED CHARCOAL	12 [hp_X] in 1 g
CARBON DISULFIDE (UNII: S54S8B99E8) (CARBON DISULFIDE - UNII:S54S8B99E8)	CARBON DISULFIDE	12 [hp_X] in 1 g
CAUSTICUM (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)	CAUSTICUM	12 [hp_X] in 1 g
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	30 [hp_X] in 1 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	30 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

ALOE VERA LEAF (UNII: ZY81Z83H0X)
ARNICA MONTANA (UNII: O80TY208ZW)
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)
LARREA TRIDENTATA TOP (UNII: PK0TXD049P)
COMFREY LEAF (UNII: DG4F8T839X)
EDETATE DISODIUM (UNII: 7FLD91C86K)
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AHIRAF4M)
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)
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)
PHYTOLACCA AMERICANA FRUIT (UNII: WE63661499)
PHYTOLACCA AMERICANA ROOT (UNII: 11E6V18VEG)
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)
ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43846-0039-2	1 in 1 CARTON	12/29/2014	
1	NDC:43846-0039-1	14 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/29/2014	

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0039) , api manufacture(43846-0039) , label(43846-0039) , pack(43846-0039)