

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

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.

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

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INACTIVE INGREDIENTS:

Aloe Vera, Arnica (Flower), Carbomer, Chaparral (leaf) Comfrey (leaf), Edetate Disodium, Lavender (buds), Lemon Balm, PEG 33, PEG 8 Dimethicone, PEG 14, Poke (Berry), Poke (root), Potassium Sorbate, Purified Water, Sodium Hydroxide, St. John's Wort, Vitamin C, Vitamin E, White Willow

(bark), Yarrow (flower).

QUESTIONS:

Dist. By Peaceful Mountain, Inc.

Woodbine, IA 51579

888-303-3388

www.peacefulmountain.com

PACKAGE LABEL DISPLAY:

peaceful mountain

THE HEIGHT OF HEALTH

ACNE RESCUE

Net wt. 0.25 oz (7g)

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

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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 - Condition worsens - Symptoms last more than 7 days.

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, Edicate Disodium, Lavender Bush, Lemon Balm Leaf, Natural Plant Extract, PEG-33 & PEG-8 Dimethacrylate & PEG-14, Phenoxylethanol & 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.

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ACNE RESCUE

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0040
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) (COLLOIDAL SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	30 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
LARREA TRIDENTATA TOP (UNII: PK0TXD049P)	
COMFREY LEAF (UNII: DG4F8T839X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	
LEMON BALM OIL (UNII: MJ76269K9S)	
OREGANO (UNII: 0E5AT8T16U)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
POLYETHYLENE GLYCOL 700 (UNII: 762678AC5R)	
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)	
ST. JOHN'S WORT (UNII: UFH8805FKA)	
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:43846-0040-1	7 g in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/10/2014	

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0040) , api manufacture(43846-0040) , label(43846-0040) , pack(43846-0040)

