

**COLD SORE RESCUE- borax, dulcamara, natrum muriaticum, ranunculus bulbosus, 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:

(in gel): 0.20% of BORAX 30X, DULCAMARA 30X, NATRUM MURIATICUM 30X,
RANUNCULUS BULBOSUS 30X, SILICEA 30X.

USES:

May temporary relief symptoms of cold sores and fever blisters such as: stinging - itching - swelling of minor herpetic skin eruptions of the face or genitals.**

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

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.

Do not use if tamper evident 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 affected area. Children under 12 years of age: Consult a doctor.

USES:

May temporary relief symptoms of cold sores and fever blisters such as: stinging - itching - swelling of minor herpetic skin eruptions of the face or genitals.**

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INACTIVE INGREDIENTS:

Water, Chaparral (Larrea Tridentata) Leaf, Comfrey (Symphytum Officinale) Leaf, St. John's Wort (Hypericum Perforatum) Aerial Parts, Poke (Phytolacca Americana) Root, Arnica (Arnica Montana) Flower, Lemon Balm (Melissa Officinalis) Leaf, White Willow (Salix Alba) Bark, Yarrow (Achillea Millefolium) Flower, English Lavender (Lavandula Angustifolia) Buds, Ascorbic Acid, Poke (Phytolacca Americana) Berries, Aloe Vera 10X Concentrate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Phenoxyethanol, Caprylyl Glycol, Sorbic Acid, PEG-33, PEG-8 Dimethicone, PEG-14, Sodium Hydroxide, Tocopherols (Soy), Edetate Disodium (EDTA), Natural Plant Extract (Origanox WS), Potassium Sorbate, Sodium Benzoate, Alcohol, Citric Acid.

QUESTIONS:

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

Dist. by Peaceful Mountain, Inc., Woodbine, IA 51579

www.peacefulmountain.com

PACKAGE LABEL DISPLAY:

homeopathic relief

May temporarily relieve cold sore and fever blisters symptoms

May help temporarily relieve stinging, burning, itching and swelling

peaceful mountain

THE HEIGHT OF HEALTH

formulated in boulder, co

cold sore rescue

homeopathic gel

Net wt. 0.25 oz. (7 g)

Directions: Apply at least 3 times daily over affected area. For external use only. Children under 12 years of age: Consult a doctor.

Active ingredients (in gel): 0.20% of Borax 30x, Dulcamara 30x, Natrum Muriaticum 30x, Ranunculus Bulbosus 30x, Silicea 30x.

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Net wt. 0.25 oz. (7 g)

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0031
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM BORATE (UNII: 91MBZ8H3QO) (BORATE ION - UNII:44OAE30D22)	SODIUM BORATE	30 [hp_X] in 1 g
SOLANUM DULCAMARA TOP (UNII: KPS1B1162N) (SOLANUM DULCAMARA TOP - UNII:KPS1B1162N)	SOLANUM DULCAMARA TOP	30 [hp_X] in 1 g
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	30 [hp_X] in 1 g
RANUNCULUS BULBOSUS WHOLE (UNII: AEQ8NXJ0MB) (RANUNCULUS BULBOSUS WHOLE - UNII:AEQ8NXJ0MB)	RANUNCULUS BULBOSUS WHOLE	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 FLOWER (UNII: OZ0E5Y15PZ)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
LARREA TRIDENTATA LEAF (UNII: PK0TXD049P)	
COMFREY LEAF (UNII: DG4F8T839X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
OREGANO (UNII: 0E5AT8T16U)	
POLYETHYLENE GLYCOL 1600 (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)	
ST. JOHN'S WORT (UNII: UFH8805FKA)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ALCOHOL (UNII: 3K9958V90M)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:43846-0031-2	1 in 1 CARTON	12/08/2014	
1	NDC:43846-0031-1	7 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			12/08/2014	

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment			
Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0031) , api manufacture(43846-0031) , label(43846-0031) , pack(43846-0031)

Revised: 4/2020

Peaceful Mountain, Inc.