

SHINGLES PAIN RELIEF- calendula officinalis, croton tiglium, natrum muriaticum, plantago major, rhus tox, sarsaparilla (smilax regelii) liquid 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 each spray): 0.21% of Calendula Officinalis 12X, Croton Tiglium 30X, Natrum Muriaticum 30X, Plantago Major 30X, Rhus Tox 30X, Sarsaparilla (Smilax Regelii) 30X.

INDICATIONS:

May temporarily relieve pain due to inflammation caused by but not limited to the following: itching and sensitivity, eruptions, blisters.**

**These statements are based upon traditional homeopathic principles. 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.

Do not get into eyes.

If symptoms persist, consult a doctor.

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:

Spray liberally on affected area as needed. Children under 12 years of age: consult a doctor.

INDICATIONS:

May temporarily relieve pain due to inflammation caused by but not limited to the following: itching and sensitivity, eruptions, blisters.**

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

INACTIVE INGREDIENTS:

Aloe Barbadensis Leaf Juice, Arnica Flower*, Chaparral Leaf*, Comfrey Leaf*, Dragon's Blood Croton Sap, English Lavender Buds*, Ionic Colloidal Silver, Lemon Balm Leaf*, PEG-33, PEG-8 Dimethicone, PEG-14, Phenoxyethanol, Caprylyl Glycol, Sorbic Acid, Poke Berries*, Poke Root*, Potassium Sorbate, Purified Water, Sodium Bicarbonate, St. John's Wort Aerial Parts*, Tocopherols (soy), Vitamin C, Whey Protein Concentrate (milk), White Willow Bark* and Yarrow Flower*.

*extract

QUESTIONS:

Dist. by Peaceful Mountain, Inc.
Woodbine, IA 51579 888-303-3388
www.peacefulmountain.com

PACKAGE LABEL DISPLAY:

peaceful mountain

THE HEIGHT OF HEALTH

shingles pain

relief

homeopathic spray

1 fl. oz. (30 mL)

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. Do not get into eyes. If symptoms persist for more than 7 days, consult a doctor. Do not use if tamper evident seal is broken or missing.

SHAKE WELL

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

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shingles pain relief

homeopathic spray

ACTIVE INGREDIENTS (in each spray):
0.21% of Calendula 12x, Croton 30x, Nat Mur 30x, Plantago 30x, Rhus Tox 30x, Sarsaparilla 30x.

1 fl. oz. (30 mL)

DIRECTIONS: Shake well and spray liberally on affected area as needed. Children under 12 years of age: consult a doctor.

INDICATIONS: May temporarily relieve pain due to inflammation caused by but not limited to the following: itching and sensitivity, eruptions, blisters.**

INACTIVE INGREDIENTS:
Aloe Vera Leaf Juice, Arnica Flower*, Caprylyl Glycol, Chaparral Leaf*, Comfrey Leaf*, Dragon's Blood Croton Sap, English Lavender Buds*, Ionic Colloidal Silver, Lemon Balm Leaf*, PEG-8 Dimethicone, PEG-14, PEG-33, Phenoxyethanol, Poke Berries*, Poke Root*, Potassium Sorbate, Purified Water, Sodium Bicarbonate, Sorbic Acid, St. John's Wort Aerial Parts*, Tocopherols (soy), Vitamin C, Whey Protein Concentrate (milk), White Willow Bark* and Yarrow Flower*.

*Extract LOT: XXXXX

SHINGLES PAIN RELIEF

calendula officinalis, croton tiglium, natrum muriaticum, plantago major, rhus tox, sarsaparilla (smilax regelii) liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0059
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	12 [hp_X] in 1 mL
CROTON TIGLIUM SEED (UNII: 0HK2GZK66E) (CROTON TIGLIUM SEED - UNII:0HK2GZK66E)	CROTON TIGLIUM SEED	30 [hp_X] in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	30 [hp_X] in 1 mL
PLANTAGO MAJOR (UNII: W2469WNO6U) (PLANTAGO MAJOR - UNII:W2469WNO6U)	PLANTAGO MAJOR	30 [hp_X] in 1 mL
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	30 [hp_X] in 1 mL
SMILAX ORNATA ROOT (UNII: 2H1576D5WG) (SARSAPARILLA - UNII:2H1576D5WG)	SMILAX ORNATA ROOT	30 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
LARREA TRIDENTATA LEAF (UNII: PK0TXD049P)	
COMFREY LEAF (UNII: DG4F8T839X)	
CROTON LECHLERI RESIN (UNII: GGG6W25C63)	

LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)
SILVER (UNII: 3M4G523W1G)
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)
PEG-8 DIMETHICONE (UNII: GIA7T764OD)
POLYETHYLENE GLYCOL 700 (UNII: 762678AC5R)
PHENOXYETHANOL (UNII: H1E492ZZ3T)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
SORBIC ACID (UNII: X045WJ989B)
PHYTOLACCA AMERICANA FRUIT (UNII: WE63661499)
PHYTOLACCA AMERICANA ROOT (UNII: 11E6VI8VEG)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
WATER (UNII: 059QF0KO0R)
SODIUM BICARBONATE (UNII: 8MDF5V39QO)
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
WHEY (UNII: 8617Z5FMF6)
SALIX ALBA BARK (UNII: 205MXS71H7)
ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43846-0059-1	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/24/2016	09/04/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/24/2016	09/04/2024

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0059) , api manufacture(43846-0059) , label(43846-0059) , pack(43846-0059)