

DERMA PAIN PLUS- croton tiglium, natrum muriaticum, plantago major, rhus toxicodendron, sarsaparilla (smilax regelii) 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 Croton Tiglium 30X, Natrum Muriaticum 30X, Plantago Major 30X, Rhus Tox 30X, Sarsaparilla 30X.

INDICATIONS:

May temporarily relieve stinging pain, skin lesions, itching and burning associated with herpetic eruptions and infection.**

**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. • Do not use on broken or abraded skin.

Stop use and ask a doctor if • Rash develops Condition worsens • Symptoms last more than 7 days. • 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 liberally as needed.
- Children under 12 years of age: Consult a doctor.

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May temporarily relieve stinging pain, skin lesions, itching and burning associated with herpetic eruptions and infection.**

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INACTIVE INGREDIENTS:

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

QUESTIONS:

888-303-3388

Mon-Fri 8a.m-5p.m CST

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

www.peacefulmountain.com

PACKAGE LABEL DISPLAY:

peaceful mountain
THE HEIGHT OF HEALTH®
derma pain plus+
homeopathic gel
Net wt. 1.4 oz. (40 g)

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THE HEIGHT OF HEALTH®
derma pain plus+
homeopathic gel Net wt. 1.4 oz. (40 g)

Directions: Apply liberally as needed. For external use only. Children under 12 years of age, consult a doctor.

Uses: May temporarily relieve stinging pain, skin lesions, itching and burning associated with herpetic eruptions and infection.

Active ingredients (in gel): 0.20% of Croton Tiglium 30x, Natrum Muriaticum 30x, Plantago Major 30x, Rhus Tox 30x, Sarsaparilla 30x.

Allergy alert: • Soy

Do not use if tamper-evident seal is broken or missing.

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Drug Facts (continued)

Directions

- Apply liberally as needed.
- Children under 12 years of age: Consult a doctor.

Inactive ingredients

Water/Poke (Phytolacca americana) Berry/Chaparral (Larrea tridentata) Leaf/Comfrey (Symphytum officinale) Leaf/St. John's Wort (Hypericum perforatum) Leaf, Flower, Stem/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) Suite/Ascorbic Acid Extract, Water, Aloe Vera Leaf Juice, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Phenoxyethanol, Caprylyl Glycol, Sorbic Acid, PEG-33, PEG-8, Dimethicone, PEG-14, Sodium Hydroxide, Tocopherol (soy), Disodium EDTA, Natural Plant Extract, Potassium Sorbate, Sodium Benzoate, Ethanol and Citric Acid.

Allergy alert: • Soy

Drug Facts (continued)

Questions? 888-303-3388

Mon-Fri 8 a.m. - 5 p.m. CT
Dist. by Peaceful Mountain, Inc. • Woodbine, IA 51579
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paraben free • no petroleum • no animal testing
no artificial colors or fragrances

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

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peaceful mountain.
THE HEIGHT OF HEALTH

derma pain. plus+

homeopathic gel

itching • burning • tingling

Net wt. 1.4 oz. (40 g)

Drug Facts

Active ingredients (Purposes)

(In gel) 0.215% of Croton Tiglium 50x (Violent itching**), Natrum Muriaticum 50x (Dry Eruptions**), Plantago Major 30x (Vesicular eruptions**), Rhus Tox 30x (Vesicular eruptions**), Sarsaparilla 30x (Herpetic eruptions**)

Uses

May temporarily relieve stinging pain, skin lesions, itching and burning associated with herpetic eruptions and infection.**

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 use on broken or abraded skin. Stop use and ask a doctor if • Rash develops • Condition worsens • Symptoms last more than 7 days. • Do not use if tamper evident seal is broken or missing.

DERMA PAIN PLUS

croton tiglium, natrum muriaticum, plantago major, rhus toxicodendron, sarsaparilla (smilax regelii) gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43846-0080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CROTON TIGLIUM SEED (UNII: 0HK2GZK66E) (CROTON TIGLIUM SEED - UNII:0HK2GZK66E)	CROTON TIGLIUM SEED	30 [hp_X] in 1 g	
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	30 [hp_X] in 1 g	
PLANTAGO MAJOR WHOLE (UNII: W2469WNO6U) (PLANTAGO MAJOR - UNII:W2469WNO6U)	PLANTAGO MAJOR WHOLE	30 [hp_X] in 1 g	
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	30 [hp_X] in 1 g	
SMILAX ORNATA ROOT (UNII: 2H1576D5WG) (SARSAPARILLA - UNII:2H1576D5WG)	SMILAX ORNATA ROOT	30 [hp_X] in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PHYTOLACCA AMERICANA FRUIT (UNII: WE63661499)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBIC ACID (UNII: X045WJ989B)	

CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)
POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A)
PEG-8 DIMETHICONE (UNII: GIA7T764OD)
POLYETHYLENE GLYCOL 700 (UNII: 762678AC5R)
LARREA TRIDENTATA LEAF (UNII: PK0TXD049P)
COMFREY LEAF (UNII: DG4F8T839X)
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)
PHYTOLACCA AMERICANA ROOT (UNII: 11E6VI8VEG)
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)
SALIX ALBA BARK (UNII: 205MXS71H7)
ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
EDETATE DISODIUM (UNII: 7FLD91C86K)
OREGANO (UNII: 0E5AT8T16U)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
SODIUM BENZOATE (UNII: OJ245FE5EU)
ALCOHOL (UNII: 3K9958V90M)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43846-0080-2	1 in 1 CARTON	04/16/2021	
1	NDC:43846-0080-1	40 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/16/2021	

Labeler - Peaceful Mountain, Inc. (078430707)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43846-0080) , api manufacture(43846-0080) , label(43846-0080) , pack(43846-0080)

