

BEE - BUG BITE - pulex irritans, tarentula cubensis, apis mel., aranea diadema, arnica, formica, grindelia, hypericum, lachesis, latrodectus mactans, ledum, lycopodium, mezereum, rhus toxicodendron, tarentula hispana, theridion, vespa crabro, calendula, echinacea, hamamelis, solidago cream

Newton Laboratories, 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.

Bee - Bug Bite Cream

INDICATIONS & USAGE SECTION

Bee - Bug Bite Cream: Formulated for symptoms associated with bites and stings such as pain, burning, itching and swelling.

DOSAGE & ADMINISTRATION SECTION

Directions: EXTERNAL USE ONLY: Ages 2 and up, apply a thin coating up to four times daily to affected area. Repeat as needed or as directed by your healthcare professional. Under age 2, consult a licensed healthcare professional. Avoid eye contact; if eye contact occurs, rinse with water for at least 15 minutes. If allergic response or irritation occurs or persists, discontinue use and consult a licensed healthcare professional.

OTC - ACTIVE INGREDIENT SECTION

Pulex irritans 15x, Tarentula cubensis 15x, Apis mel. 10x, Aranea diadema 10x, Arnica 10x, Formica 10x, Grindelia 10x, Hypericum 10x, Lachesis 10x, Latrodectus mactans 10x, Ledum 10x, Lycopodium 10x, Mezereum 10x, Rhus toxicodendron 10x, Tarentula hispana 10x, Theridion 10x, Vespa crabro 10x, Arnica 3x, Calendula 3x, Echinacea 3x, Hamamelis 3x, Solidago 3x.

OTC - PURPOSE SECTION

Formulated for symptoms associated with bites and stings such as pain, burning, itching and swelling.

INACTIVE INGREDIENT SECTION

USP Purified Water, Pomace Olive Oil, El Deodorized Cocoa Butter, Beeswax (organic), Jojoba Esters, Soy Lecithin (organic), USP Glycerin, natural (organic, vegetable), USP Gluten-free, non-GMO Cane Alcohol (organic), Grapefruit Seed Extract, Plant preservatives (natural), Gluten-free, non-GMO Xanthan Gum.

QUESTIONS SECTION

www.newtonlabs.net Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 30012 Questions? 1.800.448.7256

WARNINGS SECTION

Warning: Do not use if tamper - evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.

OTC - PREGNANCY OR BREAST FEEDING SECTION

Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

PACKAGE LABEL

www.newtonlabs.net
 Newton Laboratories, Inc. FDA Est# 1051203 • Conyers, GA 30012
Questions? 1.800.448.7256
Warning: Do not use if tamper-evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.

NEWTON homeopathics 
 Nurturing Naturally Since 1987™
 NDC# 55714-2003-4

Bee~Bug Bite Cream

Formulated for symptoms associated with bites and stings such as pain, burning, itching and swelling.

1.75 oz (50 g)

Directions: EXTERNAL USE ONLY. Ages 2 and up, apply a thin coating up to four times daily to affected area. Repeat as needed or as directed by your healthcare professional. Under age 2, consult a licensed healthcare professional. Avoid eye contact; if eye contact occurs, rinse with water for at least 15 minutes. If allergic response or irritation occurs or persists, discontinue use and consult a licensed healthcare professional.

Active Ingredients: Pulex irritans 15x, Tarentula cubensis 15x, Apis mel. 10x, Aranea diadema 10x, Arnica 10x, Formica 10x, Grindelia 10x, Hypericum 10x, Lachesis 10x, Latrodectus mactans 10x, Ledum 10x, Lycopodium 10x, Mezereum 10x, Rhus toxicodendron 10x, Tarentula hispana 10x, Theridion 10x, Vespa crabro 10x, Arnica 3x, Calendula 3x, Echinacea 3x, Hamamelis 3x, Solidago 3x.

Inactive Ingredients: USP Purified water; Pomace olive oil; El deodorized cocoa butter; Beeswax (organic); Jojoba Esters; Soy lecithin (organic); USP Glycerin, natural (organic, vegetable); USP Gluten-free, non-GMO, cane alcohol (organic); Grapefruit seed extract; Plant preservatives (natural); Gluten-free, non-GMO, xanthan gum.

Stock# N224 Lot#

BEE - BUG BITE

pulex irritans, tarentula cubensis, apis mel., aranea diadema, arnica, formica, grindelia, hypericum, lachesis, latrodectus mactans, ledum, lycopodium, mezereum, rhus toxicodendron, tarentula hispana, theridion, vespa crabro, calendula, echinacea, hamamelis, solidago cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Pulex Irritans (UNII: C2DD62B8D)	Pulex Irritans	15 [hp_X]

Furex irritans (UNII: E03DD02R0R) (Furex irritans - UNII:E03DD02R0R)	Furex irritans	in 1 g
Citharacanthus Spinicus (UNII: 3Y5X6RT823) (Citharacanthus Spinicus - UNII:3Y5X6RT823)	Citharacanthus Spinicus	15 [hp_X] in 1 g
Apis Mellifera (UNII: 7S82P3R43Z) (Apis Mellifera - UNII:7S82P3R43Z)	Apis Mellifera	10 [hp_X] in 1 g
Araneus Diadematus (UNII: 6T6CO7R3Z5) (Araneus Diadematus - UNII:6T6CO7R3Z5)	Araneus Diadematus	10 [hp_X] in 1 g
Arnica Montana (UNII: O80TY208ZW) (Arnica Montana - UNII:O80TY208ZW)	Arnica Montana	10 [hp_X] in 1 g
Formica Rufa (UNII: 55H0W83JO5) (Formica Rufa - UNII:55H0W83JO5)	Formica Rufa	10 [hp_X] in 1 g
Grindelia Hirsutula Flowering Top (UNII: IDB0NAZ6AI) (Grindelia Hirsutula Flowering Top - UNII:IDB0NAZ6AI)	Grindelia Hirsutula Flowering Top	10 [hp_X] in 1 g
Hypericum Perforatum (UNII: XK4IUX8MNB) (Hypericum Perforatum - UNII:XK4IUX8MNB)	Hypericum Perforatum	10 [hp_X] in 1 g
Lachesis Muta Venom (UNII: VSW71SS07I) (Lachesis Muta Venom - UNII:VSW71SS07I)	Lachesis Muta Venom	10 [hp_X] in 1 g
Latrodectus Mactans (UNII: XJJ7QA858R) (Latrodectus Mactans - UNII:XJJ7QA858R)	Latrodectus Mactans	10 [hp_X] in 1 g
Ledum Palustre Twig (UNII: 877L01IZ0P) (Ledum Palustre Twig - UNII:877L01IZ0P)	Ledum Palustre Twig	10 [hp_X] in 1 g
Lycopodium Clavatum Spore (UNII: C88X29Y479) (Lycopodium Clavatum Spore - UNII:C88X29Y479)	Lycopodium Clavatum Spore	10 [hp_X] in 1 g
Daphne Mezereum Bark (UNII: X2N6E405GV) (Daphne Mezereum Bark - UNII:X2N6E405GV)	Daphne Mezereum Bark	10 [hp_X] in 1 g
Toxicodendron Pubescens Leaf (UNII: 6IO182RP7A) (Toxicodendron Pubescens Leaf - UNII:6IO182RP7A)	Toxicodendron Pubescens Leaf	10 [hp_X] in 1 g
Lycosa Tarantula (UNII: 86M454L2TT) (Lycosa Tarantula - UNII:86M454L2TT)	Lycosa Tarantula	10 [hp_X] in 1 g
Theridion Curassavicum (UNII: 9Z8D3HEM8L) (Theridion Curassavicum - UNII:9Z8D3HEM8L)	Theridion Curassavicum	10 [hp_X] in 1 g
Vespa Crabro (UNII: K3ALM8S49H) (Vespa Crabro - UNII:K3ALM8S49H)	Vespa Crabro	10 [hp_X] in 1 g
Calendula Officinalis Flowering Top (UNII: 18E7415PXQ) (Calendula Officinalis Flowering Top - UNII:18E7415PXQ)	Calendula Officinalis Flowering Top	3 [hp_X] in 1 g
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	3 [hp_X] in 1 g
Hamamelis Virginiana Root Bark/stem Bark (UNII: T7S323PKJS) (Hamamelis Virginiana Root Bark/stem Bark - UNII:T7S323PKJS)	Hamamelis Virginiana Root Bark/stem Bark	3 [hp_X] in 1 g
Solidago Virgaurea Flowering Top (UNII: 5405K23S50) (Solidago Virgaurea Flowering Top - UNII:5405K23S50)	Solidago Virgaurea Flowering Top	3 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Olive Oil (UNII: 6UYK2W1W1E)	
Cocoa Butter (UNII: 512OYT1CRR)	
Royal Jelly (UNII: L497I37F0C)	
Jobba Oil (UNII: 724GKU717M)	
Lecithin, Soybean (UNII: 1DI56QDM62)	
Glycerin (UNII: PDC6A3C0OX)	
Alcohol (UNII: 3K9958V90M)	
Citrus Paradisi Seed (UNII: 12F08874Y7)	
Xanthan Gum (UNII: TTV12P4NEE)	
Lonicera Japonica Flower (UNII: 4465L2WS4Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2003-4	50 g in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/01/2013	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-2003)

Revised: 8/2013

Newton Laboratories, Inc.