

INSECT BITES - pyrogenium, apis mel., aranea diadema, arnica, arsenicum alb, azadirachta indica, bryonia, caladium seguinum , calendula, formica, grindelia, hypericum , lachesis 15x, latroductus mactans, ledum, mezereum , nux vom., pulex irritans, rhus toxicodendron, tarentula cubensis, tarentula hispana, theridion, thuja occ., vespa crabro, echinacea, hamamelis solidago pellet

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.

Insect Bites

INDICATIONS & USAGE SECTION

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

DOSAGE & ADMINISTRATION SECTION

Directions: Ages 12 and up, take 6 pellets orally (ages 0 to 11, give 3 pellets) as needed or as directed by a healthcare professional. Under age 2, crush or dissolve pellets in purified water.

ACTIVE INGREDIENT SECTION

Pyrogenium 30x, Apis mel. 15x, Aranea diadema 15x, Arnica 15x, Arsenicum alb 15x, Azadirachta indica 15x, Bryonia 15x, Caladium seguinum 15x, Calendula 15x, Formica 15x, Grindelia 15x, Hypericum 15x, Lachesis 15x, Latroductus mactans 15x, Ledum 15x, Mezereum 15x, Nux vom. 15x, Pulex irritans 15x, Rhus toxicodendron 15x, Tarentula cubensis 15x, Tarentula hispana 15x, Theridion 15x, Thuja occ. 15x, Vespa crabro 15x, Echinacea 3x, Hamamelis 3x, Solidago 3x.

PURPOSE SECTION

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

INACTIVE INGREDIENT SECTION

Gluten-free, non-GMO, beet-derived sucrose pellets.

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.

PREGNANCY OR BREAST FEEDING SECTION


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

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
Warnings: 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.



NDC# 55714-4475-1

Insect Bites

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

1 oz (28.35 g)

Dispensed by healthcare professionals only.
Not for over-the-counter sale.

Directions: Ages 12 and up, take 6 pellets orally (ages 0 to 11, give 3 pellets) as needed or as directed by a healthcare professional. Under age 2, crush or dissolve pellets in purified water.

Active Ingredients: Pyrogenium 30x, Apis mel. 15x, Aranea diadema 15x, Arnica 15x, Arsenicum alb. 15x, Azadirachta indica 15x, Bryonia 15x, Caladium seguinum 15x, Calendula 15x, Formica 15x, Grindelia 15x, Hypericum 15x, Lachesis 15x, Latrodectus mactans 15x, Ledum 15x, Mezereum 15x, Nux vom. 15x, Pulex irritans 15x, Rhus toxicodendron 15x, Tarentula cubensis 15x, Tarentula hispana 15x, Theridion 15x, Thuja occ. 15x, Vespa crabro 15x, Echinacea 3x, Hamamelis 3x, Solidago 3x.

Inactive Ingredients: Gluten-free, non-GMO, beet-derived sucrose pellets.

Stock# **R038** Lot#

INSECT BITES

pyrogenium, apis mel., aranea diadema, arnica, arsenicum alb, azadirachta indica, bryonia, caladium seguinum, calendula, formica, grindelia, hypericum, lachesis 15x, latrodectus mactans, ledum, mezereum, nux vom., pulex irritans, rhus toxicodendron, tarentula cubensis, tarentula hispana, theridion, thuja occ., vespa crabro, echinacea, hamamelis solidago pellet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:55714-4475
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Rancid Beef (UNII: 29SUH5R3HU) (Rancid Beef - UNII:29SUH5R3HU)	Rancid Beef	30 [hp_X] in 1 g
Apis Mellifera (UNII: 7S82P3R43Z) (Apis Mellifera - UNII:7S82P3R43Z)	Apis Mellifera	15 [hp_X] in 1 g
Araneus Diadematus (UNII: 6T6CO7R3Z5) (Araneus Diadematus - UNII:6T6CO7R3Z5)	Araneus Diadematus	15 [hp_X] in 1 g

Arnica Montana (UNII: O80TY208ZW) (Arnica Montana - UNII:O80TY208ZW)	Arnica Montana	15 [hp_X] in 1 g
Arsenic Trioxide (UNII: S7V92P67HO) (Arsenic Cation (3+) - UNII:C96613F5AV)	Arsenic Trioxide	15 [hp_X] in 1 g
Azadirachta Indica Bark (UNII: G580B439YI) (Azadirachta Indica Bark - UNII:G580B439YI)	Azadirachta Indica Bark	15 [hp_X] in 1 g
Bryonia Alba Root (UNII: T7J046YI2B) (Bryonia Alba Root - UNII:T7J046YI2B)	Bryonia Alba Root	15 [hp_X] in 1 g
Dieffenbachia Seguine (UNII: 01800C6E6B) (Dieffenbachia Seguine - UNII:01800C6E6B)	Dieffenbachia Seguine	15 [hp_X] in 1 g
Calendula Officinalis Flowering Top (UNII: 18E7415PXQ) (Calendula Officinalis Flowering Top - UNII:18E7415PXQ)	Calendula Officinalis Flowering Top	15 [hp_X] in 1 g
Formica Rufa (UNII: 55H0W83JO5) (Formica Rufa - UNII:55H0W83JO5)	Formica Rufa	15 [hp_X] in 1 g
Grindelia Hirsutula Flowering Top (UNII: IDB0NAZ6AI) (Grindelia Hirsutula Flowering Top - UNII:IDB0NAZ6AI)	Grindelia Hirsutula Flowering Top	15 [hp_X] in 1 g
Hypericum Perforatum (UNII: XK4IUX8MNB) (Hypericum Perforatum - UNII:XK4IUX8MNB)	Hypericum Perforatum	15 [hp_X] in 1 g
Lachesis Muta Venom (UNII: VSW71SS07I) (Lachesis Muta Venom - UNII:VSW71SS07I)	Lachesis Muta Venom	15 [hp_X] in 1 g
Latrodectus Mactans (UNII: XJJ7QA858R) (Latrodectus Mactans - UNII:XJJ7QA858R)	Latrodectus Mactans	15 [hp_X] in 1 g
Ledum Palustre Twig (UNII: 877L01I20P) (Ledum Palustre Twig - UNII:877L01I20P)	Ledum Palustre Twig	15 [hp_X] in 1 g
Daphne Mezereum Bark (UNII: X2N6E405GV) (Daphne Mezereum Bark - UNII:X2N6E405GV)	Daphne Mezereum Bark	15 [hp_X] in 1 g
Strychnos Nux-vomica Seed (UNII: 269XH13919) (Strychnos Nux-vomica Seed - UNII:269XH13919)	Strychnos Nux-vomica Seed	15 [hp_X] in 1 g
Pulex Irritans (UNII: L63DD62R8R) (Pulex Irritans - UNII:L63DD62R8R)	Pulex Irritans	15 [hp_X] in 1 g
Toxicodendron Pubescens Leaf (UNII: 6IO182RP7A) (Toxicodendron Pubescens Leaf - UNII:6IO182RP7A)	Toxicodendron Pubescens Leaf	15 [hp_X] in 1 g
Citharacanthus Spinicus (UNII: 3Y5X6RT823) (Citharacanthus Spinicus - UNII:3Y5X6RT823)	Citharacanthus Spinicus	15 [hp_X] in 1 g
Lycosa Tarantula (UNII: 86M454L2TT) (Lycosa Tarantula - UNII:86M454L2TT)	Lycosa Tarantula	15 [hp_X] in 1 g
Theridion Curassavicum (UNII: 9Z8D3HEM8L) (Theridion Curassavicum - UNII:9Z8D3HEM8L)	Theridion Curassavicum	15 [hp_X] in 1 g
Thuja Occidentalis Leafy Twig (UNII: 1NT28V9397) (Thuja Occidentalis Leafy Twig - UNII:1NT28V9397)	Thuja Occidentalis Leafy Twig	15 [hp_X] in 1 g
Vespa Crabro (UNII: K3ALM8S49H) (Vespa Crabro - UNII:K3ALM8S49H)	Vespa Crabro	15 [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
Sucrose (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NDC:55714-4475-1	28.35 g in 1 BOTTLE, GLASS		
2	NDC:55714-4475-2	56.7 g in 1 BOTTLE, GLASS		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved homeopathic		06/01/2011		

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-4475)

Revised: 6/2011

Newton Laboratories, Inc.