

**BUG BITES - ITCH STOPPER - pyrogenium, apis mel., aranea diadema, arnica, arsenicum alb., azadirachta indica, bryonia, caladium seguinum, calendula, formica, grindelia, hypericum, lachesis, latrodictus 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.*

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## **Bug Bites - Itch Stopper**

### **INDICATIONS & USAGE SECTION**

**Bug Bites - Itch Stopper** 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. Sensitive persons begin with 1 pellet and gradually increase to full dose.

### **OTC - 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 15, Formica 15x, Grindelia 15x, Hypericum 15x, Lachesis 15x, Latrodictus 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.

### **OTC - PURPOSE SECTION**

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

### **INACTIVE INGREDIENT SECTION**

**Inactive Ingredients:** 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.

### **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

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Newton Laboratories, Inc. FDA Est#1051203 • Conyers, GA 30012  
**Questions? 1.800.448.7256**  
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**NEWTON**  
*homeopathics*   
NDC# 55714-2275-1 *Nurturing Naturally Since 1987™*

# Bug Bites~ Itch Stopper

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

**1 oz (28.35 g)**

**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. Sensitive persons begin with 1 pellet and gradually increase to full dose.

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

*Stock# N038 Lot#*

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*Stock# N038 Lot#*

## BUG BITES - ITCH STOPPER

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### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55714-2275
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Rancid Beef</b> (UNII: 29SUH5R3HU) (Rancid Beef - UNII:29SUH5R3HU)	Rancid Beef	30 [hp_X] in 1 g
<b>Apis Mellifera</b> (UNII: 7S82P3R43Z) (Apis Mellifera - UNII:7S82P3R43Z)	Apis Mellifera	15 [hp_X] in 1 g
<b>Araneus Diadematus</b> (UNII: 6T6CO7R3Z5) (Araneus Diadematus - UNII:6T6CO7R3Z5)	Araneus Diadematus	15 [hp_X] in 1 g
<b>Arnica Montana</b> (UNII: O80TY208ZW) (Arnica Montana - UNII:O80TY208ZW)	Arnica Montana	15 [hp_X] in 1 g
<b>Arsenic Trioxide</b> (UNII: S7V92P67HO) (Arsenic Cation (3+) - UNII:C96613F5AV)	Arsenic Trioxide	15 [hp_X] in 1 g
<b>Azadirachta Indica Bark</b> (UNII: G580B439YI) (Azadirachta Indica Bark - UNII:G580B439YI)	Azadirachta Indica Bark	15 [hp_X] in 1 g
<b>Bryonia Alba Root</b> (UNII: T7J046YI2B) (Bryonia Alba Root - UNII:T7J046YI2B)	Bryonia Alba Root	15 [hp_X] in 1 g
<b>Dieffenbachia Seguine</b> (UNII: 01800C6E6B) (Dieffenbachia Seguine - UNII:01800C6E6B)	Dieffenbachia Seguine	15 [hp_X] in 1 g
<b>Calendula Officinalis Flowering Top</b> (UNII: 18E7415PXQ) (Calendula Officinalis Flowering Top - UNII:18E7415PXQ)	Calendula Officinalis Flowering Top	15 [hp_X] in 1 g
<b>Formica Rufa</b> (UNII: 55H0W83JO5) (Formica Rufa - UNII:55H0W83JO5)	Formica Rufa	15 [hp_X] in 1 g
<b>Grindelia Hirsutula Flowering Top</b> (UNII: IDB0NAZ6AI) (Grindelia Hirsutula Flowering Top - UNII:IDB0NAZ6AI)	Grindelia Hirsutula Flowering Top	15 [hp_X] in 1 g
<b>Hypericum Perforatum</b> (UNII: XK4IUX8MNB) (Hypericum Perforatum - UNII:XK4IUX8MNB)	Hypericum Perforatum	15 [hp_X] in 1 g
<b>Lachesis Muta Venom</b> (UNII: VSW71SS07I) (Lachesis Muta Venom - UNII:VSW71SS07I)	Lachesis Muta Venom	15 [hp_X] in 1 g
<b>Latrodectus Mactans</b> (UNII: XJJ7QA858R) (Latrodectus Mactans - UNII:XJJ7QA858R)	Latrodectus Mactans	15 [hp_X] in 1 g
<b>Ledum Palustre Twig</b> (UNII: 877L01IZ0P) (Ledum Palustre Twig - UNII:877L01IZ0P)	Ledum Palustre Twig	15 [hp_X] in 1 g
<b>Daphne Mezereum Bark</b> (UNII: X2N6E405GV) (Daphne Mezereum Bark - UNII:X2N6E405GV)	Daphne Mezereum Bark	15 [hp_X] in 1 g
<b>Strychnos Nux-vomica Seed</b> (UNII: 269XH13919) (Strychnos Nux-vomica Seed - UNII:269XH13919)	Strychnos Nux-vomica Seed	15 [hp_X] in 1 g
<b>Pulex Irritans</b> (UNII: L63DD62R8R) (Pulex Irritans - UNII:L63DD62R8R)	Pulex Irritans	15 [hp_X] in 1 g
<b>Toxicodendron Pubescens Leaf</b> (UNII: 6IO182RP7A) (Toxicodendron Pubescens Leaf - UNII:6IO182RP7A)	Toxicodendron Pubescens Leaf	15 [hp_X] in 1 g
<b>Citharacanthus Spinicrus</b> (UNII: 3Y5X6RT823) (Citharacanthus Spinicrus - UNII:3Y5X6RT823)	Citharacanthus Spinicrus	15 [hp_X] in 1 g

<b>Lycosa Tarantula</b> (UNII: 86M454L2TT) (Lycosa Tarantula - UNII:86M454L2TT)	Lycosa Tarantula	15 [hp_X] in 1 g
<b>Theridion Curassavicum</b> (UNII: 9Z8D3HEM8L) (Theridion Curassavicum - UNII:9Z8D3HEM8L)	Theridion Curassavicum	15 [hp_X] in 1 g
<b>Thuja Occidentalis Leafy Twig</b> (UNII: 1NT28V9397) (Thuja Occidentalis Leafy Twig - UNII:1NT28V9397)	Thuja Occidentalis Leafy Twig	15 [hp_X] in 1 g
<b>Vespa Crabro</b> (UNII: K3ALM8S49H) (Vespa Crabro - UNII:K3ALM8S49H)	Vespa Crabro	15 [hp_X] in 1 g
<b>Echinacea, Unspecified</b> (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	3 [hp_X] in 1 g
<b>Hamamelis Virginiana Root Bark/stem Bark</b> (UNII: T7S323PKJS) (Hamamelis Virginiana Root Bark/stem Bark - UNII:T7S323PKJS)	Hamamelis Virginiana Root Bark/stem Bark	3 [hp_X] in 1 g
<b>Solidago Virgaurea Flowering Top</b> (UNII: 5405K23S50) (Solidago Virgaurea Flowering Top - UNII:5405K23S50)	Solidago Virgaurea Flowering Top	3 [hp_X] in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>Sucrose</b> (UNII: C151H8M554)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2275-1	28.35 g in 1 BOTTLE, GLASS		
2	NDC:55714-2275-2	56.7 g in 1 BOTTLE, GLASS		
3	NDC:55714-2275-0	7.08 g in 1 BOTTLE, GLASS		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/01/2011	

**Labeler** - Newton Laboratories, Inc. (788793610)

**Registrant** - Newton Laboratories, Inc. (788793610)

### Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-2275)