

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

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.

Bug 2396L

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

OTC - PREGNANCY OR BREAST FEEDING SECTION

If pregnant or breast-feeding, ask a doctor before use.

WARNINGS SECTION

WARNINGS: Keep out of reach of children. Do not use if tamper-evident seal is broken or missing. If symptoms worsen or persist for more than a few days, consult a doctor. If **pregnant or breast-feeding, ask a doctor before use.**

DOSAGE & ADMINISTRATION SECTION

Ages 12 and up take 6 drops by mouth (ages 0 to 11, give 3 drops) as needed or as directed by a health professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

QUESTIONS SECTION

newtonlabs.net - Questions? 800 448-7256

Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 30013

INACTIVE INGREDIENT SECTION

USP Purified water; USP Gluten-free non-GMO, organic cane alcohol 20%.

OTC - PURPOSE SECTION

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

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Echinacea 6x, Hamamelis 6x, Solidago 6x, Apis mel. 15x, Aranea 15x, Arnica 15x, Arsenicum alb. 15x, Azadirachta 15x, Bryonia 15x, Caladium seguinum 15x, Calendula 15, Formica 15x, Grindelia 15x, Hypericum 15x, Lachesis 15x, Latrodectus mac. 15x, Ledum 15x, Mezereum 15x, Nux vom. 15x, Pulex irr. 15x, Rhus tox. 15x, Tarentula cub. 15x, Tarentula hisp. 15x, Theridion 15x, Thuja

occ. 15x, Vespa 15x, Pyrogenium 30x.

INDICATIONS & USAGE SECTION

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

PACKAGE LABEL

newtonlabs.net ~ Questions? 800.448.7256
 Newton Laboratories, Inc. FDA Est #1051203 • Compens. GA 30013
Label statements have not been reviewed by the FDA.
WARNINGS: Keep out of reach of children. Do not use if tamper-evident seal is broken or missing. If symptoms worsen or persist for more than a few days, consult a doctor. If pregnant or breast-feeding, ask a doctor before use.

NEWTON homeopathics 
 Since 1987

NDC#
55714-2396-1

Bug Bites ~ Itch Stopper

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

1 FL OZ (30 ML)

Directions: Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) as needed or as directed by a health professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

Active Ingredients: Equal parts of Echinacea 6x, Hamamelis 6x, Solidago 6x, Apis mel. 15x, Aranea 15x, Arnica 15x, Arsenicum alb. 15x, Azadirachta 15x, Bryonia 15x, Caladium seguinum 15x, Calendula 15x, Formica 15x, Grindelia 15x, Hypericum 15x, Lachesis 15x, Latrodectus mac. 15x, Ledum 15x, Mezereum 15x, Nux vom. 15x, Pulex irr. 15x, Rhus tox. 15x, Tarentula cub. 15x, Tarentula hisp. 15x, Theridion 15x, Thuja occ. 15x, Vespa 15x, Pyrogenium 30x.

Inactive Ingredients: USP Purified water; USP Gluten-free, non-GMO, organic cane alcohol 20%.

Stock# **N038** Lot#

BUG BITES - ITCH STOPPER

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2396
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CITHARACANTHUS SPINICRUS (UNII: 3Y5X6RT823) (CITHARACANTHUS SPINICRUS - UNII:3Y5X6RT823)	CITHARACANTHUS SPINICRUS	15 [hp_X] in 1 mL
LYCOSA TARANTULA (UNII: 86M454L2TT) (LYCOSA TARANTULA - UNII:86M454L2TT)	LYCOSA TARANTULA	15 [hp_X] in 1 mL
THERIDION CURASSAVICUM (UNII: 9Z8D3HEM8L) (THERIDION CURASSAVICUM - UNII:9Z8D3HEM8L)	THERIDION CURASSAVICUM	15 [hp_X] in 1 mL
THUJA OCCIDENTALIS LEAFY TWIG (UNII: 1NT28V9397) (THUJA OCCIDENTALIS	THUJA OCCIDENTALIS	15 [hp_X]

LEAFY TWIG - UNII:INT28V9397)	LEAFY TWIG	in 1 mL
VESPA CRABRO (UNII: K3ALM8S49H) (VESPA CRABRO - UNII:K3ALM8S49H)	VESPA CRABRO	15 [hp_X] in 1 mL
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	6 [hp_X] in 1 mL
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS) (HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK	6 [hp_X] in 1 mL
SOLIDAGO VIRGAUREA FLOWERING TOP (UNII: 5405K23S50) (SOLIDAGO VIRGAUREA FLOWERING TOP - UNII:5405K23S50)	SOLIDAGO VIRGAUREA FLOWERING TOP	6 [hp_X] in 1 mL
RANCID BEEF (UNII: 29SUH5R3HU) (RANCID BEEF - UNII:29SUH5R3HU)	RANCID BEEF	30 [hp_X] in 1 mL
APIS MELLIFERA (UNII: 7S82P3R43Z) (APIS MELLIFERA - UNII:7S82P3R43Z)	APIS MELLIFERA	15 [hp_X] in 1 mL
ARANEUS DIADEMATUS (UNII: 6T6CO7R3Z5) (ARANEUS DIADEMATUS - UNII:6T6CO7R3Z5)	ARANEUS DIADEMATUS	15 [hp_X] in 1 mL
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	15 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	15 [hp_X] in 1 mL
AZADIRACHTA INDICA BARK (UNII: G580B439YI) (AZADIRACHTA INDICA BARK - UNII:G580B439YI)	AZADIRACHTA INDICA BARK	15 [hp_X] in 1 mL
BRYONIA ALBA ROOT (UNII: T7J046Y2B) (BRYONIA ALBA ROOT - UNII:T7J046Y2B)	BRYONIA ALBA ROOT	15 [hp_X] in 1 mL
DIEFFENBACHIA SEGUINE (UNII: 01800C6E6B) (DIEFFENBACHIA SEGUINE - UNII:01800C6E6B)	DIEFFENBACHIA SEGUINE	15 [hp_X] in 1 mL
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	15 [hp_X] in 1 mL
FORMICA RUFA (UNII: 55H0W83JO5) (FORMICA RUFA - UNII:55H0W83JO5)	FORMICA RUFA	15 [hp_X] in 1 mL
GRINDELIA HIRSUTULA FLOWERING TOP (UNII: IDB0NAZ6AI) (GRINDELIA HIRSUTULA FLOWERING TOP - UNII:IDB0NAZ6AI)	GRINDELIA HIRSUTULA FLOWERING TOP	15 [hp_X] in 1 mL
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	15 [hp_X] in 1 mL
LACHESIS MUTA VENOM (UNII: VSW71SS07I) (LACHESIS MUTA VENOM - UNII:VSW71SS07I)	LACHESIS MUTA VENOM	15 [hp_X] in 1 mL
LATRODECTUS MACTANS (UNII: XJJ7QA858R) (LATRODECTUS MACTANS - UNII:XJJ7QA858R)	LATRODECTUS MACTANS	15 [hp_X] in 1 mL
LEDUM PALUSTRE TWIG (UNII: 877L01IZ0P) (LEDUM PALUSTRE TWIG - UNII:877L01IZ0P)	LEDUM PALUSTRE TWIG	15 [hp_X] in 1 mL
DAPHNE MEZEREUM BARK (UNII: X2N6E405GV) (DAPHNE MEZEREUM BARK - UNII:X2N6E405GV)	DAPHNE MEZEREUM BARK	15 [hp_X] in 1 mL
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	15 [hp_X] in 1 mL
PULEX IRRITANS (UNII: L63DD62R8R) (PULEX IRRITANS - UNII:L63DD62R8R)	PULEX IRRITANS	15 [hp_X] in 1 mL
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	15 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

Marketing Start Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2396-0	15 mL in 1 BOTTLE, GLASS; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	11/05/2018	08/01/2019
2	NDC:55714-2396-1	30 mL in 1 BOTTLE, GLASS; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug	11/05/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/05/2018	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-2396)

Revised: 11/2020

Newton Laboratories, Inc.