

**FOOD ADDITIVES-** iris versicolor, solidago virgaurea, aconitum napellus, agaricus muscarius, allium cepa, allium sativum, antimonium crudum, arsenicum album, baptisia tinctoria, bovista, caffeinum, capsicum annuum, cinchona officinalis, cinnamomum, coccus cacti, cynara scolymus, fragaria vesca, gelsemium sempervirens, histaminum hydrochloricum, ipecacuanha, jequerity, juglans regia, lachesis mutus, ledum palustre, lycopodium clavatum, mentha piperita, natrum muriaticum, nux moschata, 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.*

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**Food 4835L**

## **INDICATIONS & USAGE SECTION**

Formulated for associated symptoms such as itching, swelling, headaches, indigestion, vomiting and cramping.

## **DOSAGE & ADMINISTRATION SECTION**

Directions: Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) as needed or directed by a health professional.

## **OTC - ACTIVE INGREDIENT SECTION**

Equal parts of Iris versicolor 6x, Solidago virgaurea 6x, Aconitum napellus 15x, Agaricus muscarius 15x, Allium cepa 15x, Allium sativum 15x, Antimonium crudum 15x, Arsenicum album 15x, Baptisia tinctoria 15x, Bovista 15x, Caffeinum 15x, Capsicum annuum 15x, Cinchona officinalis 15x, Cinnamomum 15x, Coccus cacti 15x, Cynara scolymus 15x, Fragaria vesca 15x, Gelsemium sempervirens 15x, Histaminum hydrochloricum 15x, Ipecacuanha 15x, Jequerity 15x, Juglans regia 15x, Lachesis mutus 15x, Ledum palustre 15x, Lycopodium clavatum 15x, Mentha piperita 15x, Natrum muriaticum 15x, Nux moschata 15x, Ova tosta 15x, Phosphorus 15x, Podophyllum peltatum 15x, Pulsatilla 15x, Rhus toxicodendron 15x, Saccharinum 15x, Saccharum lactis 15x, Sepia 15x, Sulphur 15x, Thiosinaminum 15x, Urtica urens 15x, Ustilago maidis 15x, Zingiber officinale 15x, Anacardium occidentale 16x, Ascorbicum acidum 16x, Astacus fluviatilis 16x, Glycyrrhiza glabra 16x, Lycopersicum esculentum 16x, Natrum nitricum 16x, Saccharum officinale 16x, Sinapis nigra 16x, Solanum nigrum 16x, Solanum tuberosum 16x, Torula cerevisiae 16x.

## **OTC - PURPOSE SECTION**

Formulated for associated symptoms such as itching, swelling, headaches, indigestion, vomiting and cramping.

## **INACTIVE INGREDIENT SECTION**

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

## **QUESTIONS SECTION**

newtonlabs.net - Questions? 800.448.7256

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

## 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.

## OTC - PREGNANCY OR BREAST FEEDING SECTION

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

## OTC - KEEP OUT OF REACH OF CHILDREN SECTION

**Keep out of reach of children.**

## PACKAGE LABEL

**newtonlabs.net ~ Questions? 800.448.7256**  
Newton Laboratories, Inc. FDA Est# 1051203 • Conyers, 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.

NDC#  
55714-4835-1

**NEWTON**  
*homeopathics*  
**PRO**

**Food Additives**

Formulated for associated symptoms such as itching, swelling, headaches, indigestion, vomiting and cramping.

**1 FL OZ (30 ML)**

Dispensed by health professionals - not sold over-the-counter.  
**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.  
**Active Ingredients:** Equal parts of Iris vers. 6x, Solidago 6x, Aconitum nap. 15x, Agaricus musc. 15x, Allium cepa 15x, Allium sat. 15x, Antimon. crud. 15x, Arsenicum alb. 15x, Baptisia 15x, Bovista 15x, Caffeinum 15x, Capsicum 15x, Cinchona 15x, Cinnamomum 15x, Coccus 15x, Cynara 15x, Frageria 15x, Gelsemium 15x, Histaminum hydrochloricum 15x, Ipecac. 15x, Jequirity 15x, Juglans reg. 15x, Lachesis 15x, Ledum 15x, Lycopodium 15x, Mentha pip. 15x, Nat. mur. 15x, Nux mosch. 15x, Ova tosta 15x, Phos. 15x, Podoph. pelt. 15x, Pulsatilla 15x, Rhus tox. 15x, Saccharinum 15x, Sac. lac. 15x, Sepia 15x, Sulphur 15x, Thiosinaminum 15x, Urtica ur. 15x, Ustilago maidis 15x., Zingiber 15x, Anacard. occ. 16x, Ascorbicum ac. 16x, Astacus 16x, Glycyrrhiza 16x, Lycopersicum 16x, Nat. nitricum 16x, Saccharum off. 16x, Sinapis nig. 16x, Solanum nig. 16x, Solanum tub. 16x, Torula cerevisiae 16x.  
**Inactive Ingredients:** USP Purified water; USP Gluten-free, non-GMO, organic cane alcohol 20%.

Stock# **R085** Lot#

## FOOD ADDITIVES

iris versicolor, solidago virgaurea, aconitum napellus, agaricus muscarius, allium cepa, allium sativum, antimonium crudum, arsenicum album, baptisia tinctoria, bovista, caffeinum, capsicum annuum, cinchona officinalis, cinnamomum, coccus cacti, cynara scolymus, fragaria vesca, gelsemium sempervirens, histaminum hydrochloricum, ipecacuanha, jequerity, juglans regia, lachesis mutus, ledum palustre, lycopodium clavatum, mentha piperita, natrum muriaticum, nux moschata, liquid

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:55714-4835 |
| <b>Route of Administration</b> | ORAL           |                           |                |

| Active Ingredient/Active Moiety   |                                    |                   |
|---|------------------------------------|-------------------|
| Ingredient Name   | Basis of Strength                  | Strength          |
| <b>BLACK MUSTARD SEED</b> (UNII: 8LTY55LQ8D) (BLACK MUSTARD SEED - UNII:8LTY55LQ8D)                                 | BLACK MUSTARD SEED                 | 16 [hp_X] in 1 mL |
| <b>SOLANUM NIGRUM WHOLE</b> (UNII: 0FMD6WV47M) (SOLANUM NIGRUM WHOLE - UNII:0FMD6WV47M)                             | SOLANUM NIGRUM WHOLE               | 16 [hp_X] in 1 mL |
| <b>ANACARDIUM OCCIDENTALE FRUIT</b> (UNII: 4A10JR4E7E) (ANACARDIUM OCCIDENTALE FRUIT - UNII:4A10JR4E7E)             | ANACARDIUM OCCIDENTALE FRUIT       | 16 [hp_X] in 1 mL |
| <b>SOLANUM LYCOPERSICUM</b> (UNII: 0243Q4990L) (SOLANUM LYCOPERSICUM - UNII:0243Q4990L)                             | SOLANUM LYCOPERSICUM               | 16 [hp_X] in 1 mL |
| <b>SODIUM NITRITE</b> (UNII: M0KG633D4F) (NITRITE ION - UNII:J39976L608)  | SODIUM NITRITE                     | 16 [hp_X] in 1 mL |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)  | SODIUM CHLORIDE                    | 15 [hp_X] in 1 mL |
| <b>ANEMONE PULSATILLA</b> (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)                                 | ANEMONE PULSATILLA                 | 15 [hp_X] in 1 mL |
| <b>TOXICODENDRON PUBESCENS LEAF</b> (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)             | TOXICODENDRON PUBESCENS LEAF       | 15 [hp_X] in 1 mL |
| <b>ALLYLTHIOUREA</b> (UNII: 706IDJ14B7) (ALLYLTHIOUREA - UNII:706IDJ14B7)   | ALLYLTHIOUREA                      | 15 [hp_X] in 1 mL |
| <b>IRIS VERSICOLOR ROOT</b> (UNII: X43D4L3DQC) (IRIS VERSICOLOR ROOT - UNII:X43D4L3DQC)                             | IRIS VERSICOLOR ROOT               | 6 [hp_X] in 1 mL  |
| <b>IPECAC</b> (UNII: 62I3C8233L) (IPECAC - UNII:62I3C8233L)   | IPECAC                             | 15 [hp_X] in 1 mL |
| <b>ACONITUM NAPELLUS</b> (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)                                   | ACONITUM NAPELLUS                  | 15 [hp_X] in 1 mL |
| <b>AMANITA MUSCARIA FRUITING BODY</b> (UNII: DIF093I037) (AMANITA MUSCARIA FRUITING BODY - UNII:DIF093I037)         | AMANITA MUSCARIA FRUITING BODY     | 15 [hp_X] in 1 mL |
| <b>ONION</b> (UNII: 492225Q21H) (ONION - UNII:492225Q21H)   | ONION                              | 15 [hp_X] in 1 mL |
| <b>GARLIC</b> (UNII: V1V998DC17) (GARLIC - UNII:V1V998DC17)   | GARLIC                             | 15 [hp_X] in 1 mL |
| <b>PHOSPHORUS</b> (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)   | PHOSPHORUS                         | 15 [hp_X] in 1 mL |
| <b>SACCHARIN</b> (UNII: FST467XS7D) (SACCHARIN - UNII:FST467XS7D)   | SACCHARIN                          | 15 [hp_X] in 1 mL |
| <b>ANTIMONY TRISULFIDE</b> (UNII: F79059A38U) (ANTIMONY CATION (3+) - UNII:069647RPT5)                              | ANTIMONY TRISULFIDE                | 15 [hp_X] in 1 mL |
| <b>ARSENIC TRIOXIDE</b> (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)                                  | ARSENIC TRIOXIDE                   | 15 [hp_X] in 1 mL |
| <b>BAPTISIA TINCTORIA ROOT</b> (UNII: 5EF0HWI5WU) (BAPTISIA TINCTORIA ROOT - UNII:5EF0HWI5WU)                       | BAPTISIA TINCTORIA ROOT            | 15 [hp_X] in 1 mL |
| <b>LYCOPERDON UTRIFORME FRUITING BODY</b> (UNII: K2A74U428F) (LYCOPERDON UTRIFORME FRUITING BODY - UNII:K2A74U428F) | LYCOPERDON UTRIFORME FRUITING BODY | 15 [hp_X] in 1 mL |
| <b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)   | CAFFEINE                           | 15 [hp_X] in 1 mL |
| <b>CAPSICUM</b> (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)   | CAPSICUM                           | 15 [hp_X] in 1 mL |
| <b>CINCHONA OFFICINALIS BARK</b> (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB)                   | CINCHONA OFFICINALIS BARK          | 15 [hp_X] in 1 mL |
| <b>CINNAMON</b> (UNII: 5S29HWU6QB) (CINNAMON - UNII:5S29HWU6QB)   | CINNAMON                           | 15 [hp_X] in 1 mL |
| <b>PROTORTONIA CACTI</b> (UNII: LZB7TFX1LT) (PROTORTONIA CACTI - UNII:LZB7TFX1LT)                                   | PROTORTONIA CACTI                  | 15 [hp_X] in 1 mL |
| <b>CYNARA SCOLYMUS LEAF</b> (UNII: B71UA545DE) (CYNARA SCOLYMUS LEAF - UNII:B71UA545DE)                             | CYNARA SCOLYMUS LEAF               | 15 [hp_X] in 1 mL |
| <b>ALPINE STRAWBERRY</b> (UNII: CG6IX3GCMU) (ALPINE STRAWBERRY - UNII:CG6IX3GCMU)                                   | ALPINE STRAWBERRY                  | 15 [hp_X] in 1 mL |
| <b>GELSEMIUM SEMPERVIRENS ROOT</b> (UNII: 639KR60Q1Q) (GELSEMIUM  | GELSEMIUM SEMPERVIRENS             | 15 [hp_X]         |

|   |                                    |                   |
|---|------------------------------------|-------------------|
| SEMPERVIRENS ROOT - UNII:639KR60Q1Q)  | ROOT                               | in 1 mL           |
| <b>HISTAMINE DIHYDROCHLORIDE</b> (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)                                   | HISTAMINE DIHYDROCHLORIDE          | 15 [hp_X] in 1 mL |
| <b>SOLIDAGO VIRGAUREA FLOWERING TOP</b> (UNII: 5405K23S50) (SOLIDAGO VIRGAUREA FLOWERING TOP - UNII:5405K23S50)     | SOLIDAGO VIRGAUREA FLOWERING TOP   | 6 [hp_X] in 1 mL  |
| <b>URTICA URENS</b> (UNII: IHN2NQ5OF9) (URTICA URENS - UNII:IHN2NQ5OF9)   | URTICA URENS                       | 15 [hp_X] in 1 mL |
| <b>GINGER</b> (UNII: C5529G5JPQ) (GINGER - UNII:C5529G5JPQ)   | GINGER                             | 15 [hp_X] in 1 mL |
| <b>SUCROSE</b> (UNII: C151H8M554) (SUCROSE - UNII:C151H8M554)   | SUCROSE                            | 16 [hp_X] in 1 mL |
| <b>MENTHA PIPERITA</b> (UNII: 79M2M2UDA9) (MENTHA PIPERITA - UNII:79M2M2UDA9)                                       | MENTHA PIPERITA                    | 15 [hp_X] in 1 mL |
| <b>ABRUS PRECATORIUS SEED</b> (UNII: 3OM8I6L7CD) (ABRUS PRECATORIUS SEED - UNII:3OM8I6L7CD)                         | ABRUS PRECATORIUS SEED             | 15 [hp_X] in 1 mL |
| <b>JUGLANS REGIA LEAF</b> (UNII: 85HKB87105) (JUGLANS REGIA LEAF - UNII:85HKB87105)                                 | JUGLANS REGIA LEAF                 | 15 [hp_X] in 1 mL |
| <b>USTILAGO MAYDIS</b> (UNII: 4K7Z7K7SWG) (USTILAGO MAYDIS - UNII:4K7Z7K7SWG)                                       | USTILAGO MAYDIS                    | 15 [hp_X] in 1 mL |
| <b>LACHESIS MUTA VENOM</b> (UNII: VSW71SS07I) (LACHESIS MUTA VENOM - UNII:VSW71SS07I)                               | LACHESIS MUTA VENOM                | 15 [hp_X] in 1 mL |
| <b>NUTMEG</b> (UNII: AEE24M3MQ9) (NUTMEG - UNII:AEE24M3MQ9)   | NUTMEG                             | 15 [hp_X] in 1 mL |
| <b>PODOPHYLLUM</b> (UNII: 2S713A4VP3) (PODOPHYLLUM - UNII:2S713A4VP3)   | PODOPHYLLUM                        | 15 [hp_X] in 1 mL |
| <b>SULFUR</b> (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)   | SULFUR                             | 15 [hp_X] in 1 mL |
| <b>ASTACUS ASTACUS</b> (UNII: V0551986XQ) (ASTACUS ASTACUS - UNII:V0551986XQ)                                       | ASTACUS ASTACUS                    | 16 [hp_X] in 1 mL |
| <b>GLYCYRRHIZA GLABRA</b> (UNII: 2788Z9758H) (GLYCYRRHIZA GLABRA - UNII:2788Z9758H)                                 | GLYCYRRHIZA GLABRA                 | 16 [hp_X] in 1 mL |
| <b>SOLANUM TUBEROSUM</b> (UNII: 2A8I57T4MX) (SOLANUM TUBEROSUM - UNII:2A8I57T4MX)                                   | SOLANUM TUBEROSUM                  | 16 [hp_X] in 1 mL |
| <b>SACCHAROMYCES CEREVISIAE</b> (UNII: 978D8U419H) (SACCHAROMYCES CEREVISIAE - UNII:978D8U419H)                     | SACCHAROMYCES CEREVISIAE           | 16 [hp_X] in 1 mL |
| <b>LACTOSE, UNSPECIFIED FORM</b> (UNII: J2B2A4N98G) (ANHYDROUS LACTOSE - UNII:3SY5LH9PMK)                           | LACTOSE, UNSPECIFIED FORM          | 15 [hp_X] in 1 mL |
| <b>SEPIA OFFICINALIS JUICE</b> (UNII: QDL83WN8C2) (SEPIA OFFICINALIS JUICE - UNII:QDL83WN8C2)                       | SEPIA OFFICINALIS JUICE            | 15 [hp_X] in 1 mL |
| <b>EGG SHELL, COOKED</b> (UNII: 24HBF856C8) (EGG SHELL, COOKED - UNII:24HBF856C8)                                   | EGG SHELL, COOKED                  | 15 [hp_X] in 1 mL |
| <b>LYCOPODIUM CLAVATUM SPORE</b> (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)                   | LYCOPODIUM CLAVATUM SPORE          | 15 [hp_X] in 1 mL |
| <b>RHODODENDRON TOMENTOSUM LEAFY TWIG</b> (UNII: 877L01IZ0P) (RHODODENDRON TOMENTOSUM LEAFY TWIG - UNII:877L01IZ0P) | RHODODENDRON TOMENTOSUM LEAFY TWIG | 15 [hp_X] in 1 mL |
| <b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)   | ASCORBIC ACID                      | 16 [hp_X] in 1 mL |

### Inactive Ingredients

| Ingredient Name                   | Strength |
|-----------------------------------|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)   |          |
| <b>ALCOHOL</b> (UNII: 3K9958V90M) |          |

### Packaging

| Marketing Start | Marketing End |
|-----------------|---------------|
|                 |               |

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:55714-4835-1 | 30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product | 09/02/2019           |                    |

  

| Marketing Information  |  |                      |                    |
|------------------------|--|----------------------|--------------------|
| Marketing Category     | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| unapproved homeopathic |  | 09/02/2019           |                    |

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

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

| Establishment             |         |           |                         |
|---------------------------|---------|-----------|-------------------------|
| Name                      | Address | ID/FEI    | Business Operations     |
| Newton Laboratories, Inc. |         | 788793610 | manufacture(55714-4835) |

Revised: 12/2020

Newton Laboratories, Inc.