

DAIRY-GRAIN-NIGHTSHADE- iris vers., solidago, antimon. crud., arg. nit., arsenicum alb., avena, baptisia, belladonna, bryonia, capsicum, carduus ben., cinchona, dulcamara, fagopyrum, gelsemium, hyoscyamus, ipecac., lac vac., lachesis, lycopodium, nat. mur., phos., podoph. pelt., pulsatilla, rhus tox., sac. lac., secale, sepia, stramonium, tabacum, triticum, ustilago maidis, verbascum, lycopersicum, solanum nig., solanum tub., stigmata, torula cerevisiae. 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.

Dairy 4832L

INDICATIONS & USAGE SECTION

Formulated for symptoms associated with sensitivity and intolerance to dairy, grain and nightshade foods.

DOSAGE & ADMINISTRATION SECTION

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.

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Iris versicolor 6x, Solidago virgaurea 6x, Antimonium crudum 15x, Argentum nitricum 15x, Arsenicum album 15x, Avena sativa 15x, Baptisia tinctoria 15x, Belladonna 15x, Bryonia 15x, Capsicum annuum 15x, Carduus benedictus 15x, Cinchona officinalis 15x, Dulcamara 15x, Fagopyrum esculentum 15x, Gelsemium sempervirens 15x, Hyoscyamus niger 15x, Ipecacuanha 15x, Lac vaccinum 15x, Lachesis mutus 15x, Lycopodium clavatum 15x, Natrum muriaticum 15x, Phosphorus 15x, Podophyllum peltatum 15x, Pulsatilla 15x, Rhus toxicodendron 15x, Saccharum lactis 15x, Secale cornutum 15x, Sepia 15x, Stramonium 15x, Tabacum 15x, Triticum repens 15x, Ustilago maidis 15x, Verbascum thapsus 15x, Lycopersicum esculentum 16x, Solanum nigrum 16x, Solanum tuberosum 16x, Stigmata maidis 16x, Torula cerevisiae 16x.

OTC - PURPOSE SECTION

Formulated for symptoms associated with sensitivity and intolerance to dairy, grain and nightshade foods.

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.

NEWTON homeopathics™ PRO
 NDC# 55714-4832-1
Dairy~Grain ~Nightshades
 Formulated for symptoms associated with sensitivity and intolerance to dairy, grain and nightshade foods.
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, Antimon. crud. 15x, Arg. nit. 15x, Arsenicum alb. 15x, Avena 15x, Baptisia 15x, Belladonna 15x, Bryonia 15x, Capsicum 15x, Carduus ben. 15x, Cinchona 15x, Dulcamara 15x, Fagopyrum 15x, Gelsemium 15x, Hyoscyamus 15x, Ipecac. 15x, Lac vac. 15x, Lachesis 15x, Lycopodium 15x, Nat. mur. 15x, Phos. 15x, Podoph. pelt. 15x, Pulsatilla 15x, Rhus tox. 15x, Sac. lac. 15x, Secale 15x, Sepia 15x, Stramonium 15x, Tabacum 15x, Triticum 15x, Ustilago maidis 15x, Verbascum 15x, Lycopersicum 16x, Solanum nig. 16x, Solanum tub. 16x, Stigmata 16x, Torula cerevisiae 16x.
Inactive Ingredients: USP Purified water; USP Gluten-free, non-GMO, organic cane alcohol 20%.
 Stock# R087 Lot#

DAIRY-GRAIN-NIGHTSHADE

iris vers., solidago, antimon. crud., arg. nit., arsenicum alb., avena, baptisia, belladonna, bryonia, capsicum, carduus ben., cinchona, dulcamara, fagopyrum, gelsemium, hyoscyamus, ipecac., lac vac., lachesis, lycopodium, nat. mur., phos., podoph. pelt., pulsatilla, rhus tox., sac. lac., secale, sepia, stramonium, tabacum, triticum, ustilago maidis, verbascum, lycopersicum, solanum nig., solanum tub., stigmata, torula cerevisiae. liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55714-4832 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------|------------------|
| IRIS VERSICOLOR ROOT (UNII: X43D4L3DQC) (IRIS VERSICOLOR ROOT - UNII:X43D4L3DQC) | IRIS VERSICOLOR ROOT | 6 [hp_X] in 1 mL |

| | | |
|---|----------------------------------|-------------------|
| AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F) (AVENA SATIVA FLOWERING TOP - UNII:MA9CQJ3F7F) | AVENA SATIVA FLOWERING TOP | 15 [hp_X] in 1 mL |
| CAPSICUM (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG) | CAPSICUM | 15 [hp_X] in 1 mL |
| CENTAUREA BENEDICTA (UNII: 6L5ZL09795) (CENTAUREA BENEDICTA - UNII:6L5ZL09795) | CENTAUREA BENEDICTA | 15 [hp_X] in 1 mL |
| CINCHONA OFFICINALIS BARK (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB) | CINCHONA OFFICINALIS BARK | 15 [hp_X] in 1 mL |
| CORN SILK (UNII: 7D3VB244UX) (CORN SILK - UNII:7D3VB244UX) | CORN SILK | 16 [hp_X] in 1 mL |
| ANTIMONY TRISULFIDE (UNII: F79059A38U) (ANTIMONY TRISULFIDE - UNII:F79059A38U) | ANTIMONY TRISULFIDE | 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 |
| HYOSCYAMUS NIGER (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3) | HYOSCYAMUS NIGER | 15 [hp_X] in 1 mL |
| IPECAC (UNII: 62I3C8233L) (IPECAC - UNII:62I3C8233L) | IPECAC | 15 [hp_X] in 1 mL |
| ELYMUS REPENS ROOT (UNII: 3IXW0F6P8W) (ELYMUS REPENS ROOT - UNII:3IXW0F6P8W) | ELYMUS REPENS ROOT | 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 |
| SOLANUM DULCAMARA TOP (UNII: KPS1B1162N) (SOLANUM DULCAMARA TOP - UNII:KPS1B1162N) | SOLANUM DULCAMARA TOP | 15 [hp_X] in 1 mL |
| BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B) | BRYONIA ALBA ROOT | 15 [hp_X] in 1 mL |
| FAGOPYRUM ESCULENTUM (UNII: B10M69172N) (FAGOPYRUM ESCULENTUM - UNII:B10M69172N) | FAGOPYRUM ESCULENTUM | 15 [hp_X] in 1 mL |
| GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q) | GELSEMIUM SEMPERVIRENS ROOT | 15 [hp_X] in 1 mL |
| DATURA STRAMONIUM (UNII: G6W4F0V8Z3) (DATURA STRAMONIUM - UNII:G6W4F0V8Z3) | DATURA STRAMONIUM | 15 [hp_X] in 1 mL |
| USTILAGO MAYDIS (UNII: 4K7Z7K7SWG) (USTILAGO MAYDIS - UNII:4K7Z7K7SWG) | USTILAGO MAYDIS | 15 [hp_X] in 1 mL |
| SOLANUM LYCOPERSICUM (UNII: 0243Q4990L) (SOLANUM LYCOPERSICUM - UNII:0243Q4990L) | SOLANUM LYCOPERSICUM | 16 [hp_X] in 1 mL |
| ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV) | ARSENIC TRIOXIDE | 15 [hp_X] in 1 mL |
| SOLANUM TUBEROSUM (UNII: 2A8I57T4MX) (SOLANUM TUBEROSUM - UNII:2A8I57T4MX) | SOLANUM TUBEROSUM | 16 [hp_X] in 1 mL |
| SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H) (SACCHAROMYCES CEREVISIAE - UNII:978D8U419H) | SACCHAROMYCES CEREVISIAE | 16 [hp_X] in 1 mL |
| CLAVICEPS PURPUREA SCLEROTIUM (UNII: 01G9XEA93N) (CLAVICEPS PURPUREA SCLEROTIUM - UNII:01G9XEA93N) | CLAVICEPS PURPUREA SCLEROTIUM | 15 [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 |
| SILVER NITRATE (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A) | SILVER NITRATE | 15 [hp_X] in 1 mL |
| ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H) | ATROPA BELLADONNA | 15 [hp_X] in 1 mL |
| TOBACCO LEAF (UNII: 6YR2608RSU) (TOBACCO LEAF - UNII:6YR2608RSU) | TOBACCO LEAF | 15 [hp_X] in 1 mL |
| SEPIA OFFICINALIS JUICE (UNII: QDL83WN8C2) (SEPIA OFFICINALIS JUICE - UNII:QDL83WN8C2) | SEPIA OFFICINALIS JUICE | 15 [hp_X] in 1 mL |
| PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W) | PHOSPHORUS | 15 [hp_X] in 1 mL |
| BAPTISIA TINCTORIA ROOT (UNII: 5EF0HWI5WU) (BAPTISIA TINCTORIA ROOT - UNII:5EF0HWI5WU) | BAPTISIA TINCTORIA ROOT | 15 [hp_X] in 1 mL |
| LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479) | LYCOPODIUM CLAVATUM SPORE | 15 [hp_X] in 1 mL |

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|--|---------------------------|----------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698) | SODIUM CHLORIDE | 15 [hp_X] in 1 mL |
| ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV) | ANEMONE PULSATILLA | 15 [hp_X] in 1 mL |
| LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G) (ANHYDROUS LACTOSE - UNII:3S Y5LH9PMK) | LACTOSE, UNSPECIFIED FORM | 15 [hp_X] in 1 mL |
| PODOPHYLLUM (UNII: 2S713A4VP3) (PODOPHYLLUM - UNII:2S713A4VP3) | PODOPHYLLUM | 15 [hp_X] in 1 mL |
| VERBASCUM THAPSUS (UNII: C9TD27U172) (VERBASCUM THAPSUS - UNII:C9TD27U172) | VERBASCUM THAPSUS | 15 [hp_X] in 1 mL |
| SOLANUM NIGRUM WHOLE (UNII: 0FMD6WV47M) (SOLANUM NIGRUM WHOLE - UNII:0FMD6WV47M) | SOLANUM NIGRUM WHOLE | 16 [hp_X] in 1 mL |
| COW MILK (UNII: 917J3173FT) (COW MILK - UNII:917J3173FT) | COW MILK | 15 [hp_X] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------------|----------|
| WATER (UNII: 059QF0K00R) | |
| ALCOHOL (UNII: 3K9958V90M) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:55714-4832-1 | 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(55714-4832) |

Revised: 12/2020

Newton Laboratories, Inc.