

**HYPERCALM-MENTAL FOCUS- chamomilla, echinacea, hypericum perforatum, passiflora incarnata, aconitum napellus, adrenalinum, argentum nit., arsenicum album, baptisia tinctoria, chamomilla, coffea cruda, cypripedium pubescens, digitalis purpurea, gelsemium sempervirens, humulus lupulus, hyoscyamus niger, ignatia amara, impatiens glandulifera flos, iodium, lachesis mutus, lycopodium clavatum, natrum muriaticum, nux vomica, scutellaria lateriflora, staphysagria, stramonium, theridion, veratrum viride 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.

Hypercalm 1538L

INDICATIONS AND USAGE SECTION

Formulated for associated symptoms such as impulsiveness, lack of focus, irritability and emotional or disruptive behavior.

DOSAGE & ADMINISTRATION SECTION

Directions: Children, ages 0 to 11, give 3 drops by mouth (ages 12 and up, give 6 drops) one to four times daily or as directed by a health professional. Sensitive person begin with 1 drop and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Chamomilla 6x, Echinacea 6x, Hypericum perforatum 6x, Passiflora incarnata 6x, Aconitum napellus 15x, Adrenalinum 15x, Argentum nitricum 15x, Arsenicum album 15x, Baptisia tinctoria 15x, Chamomilla 15x, Coffea cruda 15x, Cypripedium pubescens 15x, Digitalis purpurea 15x, Gelsemium sempervirens 15x, Humulus lupulus 15x, Hyoscyamus niger 15x, Ignatia amara 15x, Impatiens glandulifera flos 15x, Iodium 15x, Lachesis mutus 15x, Lycopodium clavatum 15x, Natrum muriaticum 15x, Nux vomica 15x, Scutellaria lateriflora 15x, Staphysagria 15x, Stramonium 15x, Theridion 15x, Veratrum viride 15x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as impulsiveness, lack of focus, irritability and emotional or disruptive behavior.

INACTIVE INGREDIENT SECTION

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

WARNINGS: 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
Kids

NDC #
55714-1538-1

**Hypercalm~
Mental Focus**

Formulated for associated symptoms such as impulsiveness, lack of focus, irritability and emotional or disruptive behavior.

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

Active Ingredients: Equal parts of Chamomilla 6x, Echinacea 15x, Hypericum 6x, Passiflora 6x, Aconitum nap. 15x, Adrenalinum 15x, Arg. nit. 15x, Arsenicum alb. 15x, Baptisia 15x, Chamomilla 15x, Coffea cruda 15x, Cypripedium 15x, Digitalis 15x, Gelsemium 15x, Humulus 15x, Hyoscyamus 15x, Ignatia 15x, Impatiens glan. flos 15x, Iodium 15x, Lachesis 15x, Lycopodium 15x, Nat. mur. 15x, Nux vom. 15x, Scutellaria 15x, Staphysag. 15x, Stramonium 15x, Theridion 15x, Veratrum vir. 15x.

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

Stock# **F059** Lot#

1 FL OZ (30 ML)

HYPERCALM-MENTAL FOCUS

chamomilla, echinacea, hypericum perforatum, passiflora incarnata, aconitum napellus, adrenalinum, argentum nit., arsenicum album, baptisia tinctoria, chamomilla, coffea cruda, cypripedium pubescens, digitalis purpurea, gelsemium sempervirens, humulus lupulus, hyoscyamus niger, ignatia amara, impatiens glandulifera flos, iodium, lachesis mutus, lycopodium

clavatum, natrum muriaticum, nux vomica, scutellaria lateriflora, staphysagria, stramonium, theridion, veratrum viride liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55714-1538 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|----------------------|
| ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX) | ECHINACEA, UNSPECIFIED | 6 [hp_X] in 1 mL |
| GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q) | GELSEMIUM SEMPERVIRENS ROOT | 15 [hp_X] in 1 mL |
| PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O) | PASSIFLORA INCARNATA FLOWERING TOP | 6 [hp_X] in 1 mL |
| ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD) | ACONITUM NAPELLUS | 15 [hp_X] in 1 mL |
| EPINEPHRINE (UNII: YKH834O4BH) (EPINEPHRINE - UNII:YKH834O4BH) | EPINEPHRINE | 15 [hp_X] in 1 mL |
| SILVER NITRATE (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A) | SILVER NITRATE | 15 [hp_X] in 1 mL |
| ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV) | ARSENIC TRIOXIDE | 15 [hp_X] in 1 mL |
| BAPTISIA TINCTORIA ROOT (UNII: 5EF0HW5WU) (BAPTISIA TINCTORIA ROOT - UNII:5EF0HW5WU) | BAPTISIA TINCTORIA ROOT | 15 [hp_X] in 1 mL |
| MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ) | MATRICARIA CHAMOMILLA | 15 [hp_X] in 1 mL |
| ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72) | ARABICA COFFEE BEAN | 15 [hp_X] in 1 mL |
| CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS ROOT (UNII: 21Y9GZ1LZA) (CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS ROOT - UNII:21Y9GZ1LZA) | CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS ROOT | 15 [hp_X] in 1 mL |
| DIGITALIS (UNII: F1T8QT9U8B) (DIGITALIS - UNII:F1T8QT9U8B) | DIGITALIS | 15 [hp_X] in 1 mL |
| HYOSCYAMUS NIGER (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3) | HYOSCYAMUS NIGER | 15 [hp_X] in 1 mL |
| STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K) | STRYCHNOS IGNATII SEED | 15 [hp_X] in 1 mL |
| IMPATIENS GLANDULIFERA FLOWER (UNII: AJU5O1A5ZV) (IMPATIENS GLANDULIFERA FLOWER - UNII:AJU5O1A5ZV) | IMPATIENS GLANDULIFERA FLOWER | 15 [hp_X] in 1 mL |
| IODINE (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4) | IODINE | 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 |
| LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479) | LYCOPODIUM CLAVATUM SPORE | 15 [hp_X] in 1 mL |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37) | SODIUM CHLORIDE | 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 |
| SCUTELLARIA LATERIFLORA WHOLE (UNII: 7BP4DH5PDC) (SCUTELLARIA LATERIFLORA WHOLE - UNII:7BP4DH5PDC) | SCUTELLARIA LATERIFLORA WHOLE | 15 [hp_X] in 1 mL |
| DELPHINIUM STAPHISAGRIA SEED (UNII: 00543AP1JV) (DELPHINIUM STAPHISAGRIA SEED - UNII:00543AP1JV) | DELPHINIUM STAPHISAGRIA SEED | 15 [hp_X] in 1 mL |
| DATURA STRAMONIUM (UNII: G6W4F0V8Z3) (DATURA STRAMONIUM - UNII:G6W4F0V8Z3) | DATURA STRAMONIUM | 15 [hp_X] in 1 mL |

| | | |
|---|------------------------|----------------------|
| UNII:G6W4F0V8Z3) | DATURA STRAMONIUM | in 1 mL |
| THERIDION CURASSAVICUM (UNII: 9Z8D3HEM8L) (THERIDION CURASSAVICUM - UNII:9Z8D3HEM8L) | THERIDION CURASSAVICUM | 15 [hp_X] in 1 mL |
| VERATRUM VIRIDE ROOT (UNII: 197B3Q7T5Q) (VERATRUM VIRIDE ROOT - UNII:197B3Q7T5Q) | VERATRUM VIRIDE ROOT | 15 [hp_X] in 1 mL |
| HOPS (UNII: 01G73H6H83) (HOPS - UNII:01G73H6H83) | HOPS | 15 [hp_X] in 1 mL |
| HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB) | HYPERICUM PERFORATUM | 6 [hp_X] in 1 mL |

Inactive Ingredients

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:55714-1538-1 | 30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product | 06/01/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved homeopathic | | 06/01/2023 | |

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|-------------------------|
| Newton Laboratories, Inc. | | 788793610 | manufacture(55714-1538) |

Revised: 6/2023

Newton Laboratories, Inc.