

**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 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.

Hypercalm 1738P

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 pellets by mouth (ages 12 and up, give 6 pellets) one to four times daily or as directed by a health professional. Under age 2, crush/dissolve pellets in purified water. Sensitive person begin with 1 pellet 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

Gluten-free, non-GMO, organic beet-derived sucrose (lactose-free) pellets.

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#
55714-1738-1

**Hypercalm~
Mental Focus**

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

1 OZ (28 G)

Directions: Children, ages 0 to 11, give 3 pellets by mouth (ages 12 and up, give 6 pellets) one to four times daily or as directed by a health professional. Under age 2, crush/dissolve pellets in purified water. Sensitive persons begin with 1 pellet and gradually increase to full dose.

Active Ingredients: Equal parts of Chamomilla 6x, Echinacea 6x, 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: Gluten-free, non-GMO, organic beet-derived sucrose (lactose-free) pellets.

Stock# F059 Lot#

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 pellet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-1738
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 g
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	15 [hp_X] in 1 g
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O)	PASSIFLORA INCARNATA FLOWERING TOP	6 [hp_X] in 1 g
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	15 [hp_X] in 1 g
EPINEPHRINE (UNII: YKH834O4BH) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE	15 [hp_X] in 1 g
SILVER NITRATE (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A)	SILVER NITRATE	15 [hp_X] in 1 g
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	15 [hp_X] in 1 g
BAPTISIA TINCTORIA ROOT (UNII: 5EF0HM5WU) (BAPTISIA TINCTORIA ROOT - UNII:5EF0HM5WU)	BAPTISIA TINCTORIA ROOT	15 [hp_X] in 1 g
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	15 [hp_X] in 1 g
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	15 [hp_X] in 1 g
CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS ROOT (UNII: 21Y9GZ1LZA) (CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS ROOT - UNII:21Y9GZ1LZA)	CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS ROOT	15 [hp_X] in 1 g
DIGITALIS (UNII: F1T8QT9U8B) (DIGITALIS - UNII:F1T8QT9U8B)	DIGITALIS	15 [hp_X] in 1 g
HYOSCYAMUS NIGER (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3)	HYOSCYAMUS NIGER	15 [hp_X] in 1 g
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	15 [hp_X] in 1 g
IMPATIENS GLANDULIFERA FLOWER (UNII: AJU5O1A5ZV) (IMPATIENS GLANDULIFERA FLOWER - UNII:AJU5O1A5ZV)	IMPATIENS GLANDULIFERA FLOWER	15 [hp_X] in 1 g
IODINE (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	15 [hp_X] in 1 g
LACHESIS MUTA VENOM (UNII: VSW71SS07I) (LACHESIS MUTA VENOM - UNII:VSW71SS07I)	LACHESIS MUTA VENOM	15 [hp_X] in 1 g
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	15 [hp_X] in 1 g
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	15 [hp_X] in 1 g
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	15 [hp_X] in 1 g
SCUTELLARIA LATERIFLORA WHOLE (UNII: 7BP4DH5PDC) (SCUTELLARIA LATERIFLORA WHOLE - UNII:7BP4DH5PDC)	SCUTELLARIA LATERIFLORA WHOLE	15 [hp_X] in 1 g
DELPHINIUM STAPHISAGRIA SEED (UNII: 00543AP1JV) (DELPHINIUM STAPHISAGRIA SEED - UNII:00543AP1JV)	DELPHINIUM STAPHISAGRIA SEED	15 [hp_X] in 1 g
DATURA STRAMONIUM (UNII: G6W4F0V8Z3) (DATURA STRAMONIUM -	DATURA STRAMONIUM	15 [hp_X]

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

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-1738-1	28 g 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(55714-1738)

Revised: 6/2023

Newton Laboratories, Inc.