

**HEADACHE-MIGRAINE- elaps corallinus, arsenicum alb., belladonna, bryonia, carduus benedictus, cimicifuga, coffea cruda, convallaria, crotalus horridus, digitalis, gelsemium, glonoinum, ignatia, lachesis, merc. viv., naja, nux vom., phosphorus, rhus toxicodendron, sanguinaria, secale, vipera berus, apis mel., hypericum, thuja occ.. 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.

Headache 4798L

INDICATIONS & USAGE SECTION

Formulated for associated symptoms such as throbbing pain, pressure, congestion, dizziness, nausea and light sensitivity.

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 Apis mellifica 6x, Hypericum perforatum 6x, Thuja occidentalis 6x, Arsenicum album 15x, Belladonna 15x, Bryonia 15x, Carduus benedictus 15x, Cimicifuga racemosa 15x, Coffea cruda 15x, Convallaria majalis 15x, Crotalus horridus 15x, Digitalis purpurea 15x, Gelsemium sempervirens 15x, Glonoinum 15x, Ignatia amara 15x, Lachesis mutus 15x, Mercurius vivus 15x, Naja tripudians 15x, Nux vomica 15x, Phosphorus 15x, Rhus toxicodendron 15x, Sanguinaria canadensis 15x, Secale cornutum 15x, Vipera berus 15x, Elaps corallinus 30x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as throbbing pain, pressure, congestion, dizziness, nausea and light sensitivity.

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

Keep out of reach of children

PACKAGE LABEL

HEADACHE-MIGRAINE

elaps corallinus, arsenicum alb., belladonna, bryonia, carduus benedictus, cimicifuga, coffea cruda, convallaria, crotales horridus, digitalis, gelsemium, glonoinum, ignatia, lachesis, merc. viv., naja, nux vom., phosphorus, rhus toxicodendron, sanguinaria, secale, vipera berus, apis mel., hypericum, thuja occ.. liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-4798
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICRURUS CORALLINUS VENOM (UNII: V0S6H36980) (MICRURUS CORALLINUS VENOM - UNII:V0S6H36980)	MICRURUS CORALLINUS VENOM	30 [hp_X] in 1 mL
ARSENIC TRIO XIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIO XIDE	15 [hp_X] in 1 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	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

CENTAUREA BENEDICTA (UNII: 6L5ZL09795) (CENTAUREA BENEDICTA - UNII:6L5ZL09795)	CENTAUREA BENEDICTA	15 [hp_X] in 1 mL
BLACK COHOSH (UNII: K73E24S6X9) (BLACK COHOSH - UNII:K73E24S6X9)	BLACK COHOSH	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
CONVALLARIA MAJALIS (UNII: QHH4HVF5QE) (CONVALLARIA MAJALIS - UNII:QHH4HVF5QE)	CONVALLARIA MAJALIS	15 [hp_X] in 1 mL
CROTALUS HORRIDUS HORRIDUS VENOM (UNII: YHA2XLJ956) (CROTALUS HORRIDUS HORRIDUS VENOM - UNII:YHA2XLJ956)	CROTALUS HORRIDUS HORRIDUS VENOM	15 [hp_X] in 1 mL
DIGITALIS (UNII: FIT8QT9U8B) (DIGITALIS - UNII:FIT8QT9U8B)	DIGITALIS	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
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	15 [hp_X] in 1 mL
NITROGLYCERIN (UNII: G59M7S0WS3) (NITROGLYCERIN - UNII:G59M7S0WS3)	NITROGLYCERIN	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
MERCURY (UNII: FXS1BY2PGL) (MERCURY - UNII:FXS1BY2PGL)	MERCURY	15 [hp_X] in 1 mL
NAJA NAJA VENOM (UNII: ZZ4AG7L7VM) (NAJA NAJA VENOM - UNII:ZZ4AG7L7VM)	NAJA NAJA VENOM	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
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	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
SANGUINARIA CANADENSIS ROOT (UNII: N9288CD508) (SANGUINARIA CANADENSIS ROOT - UNII:N9288CD508)	SANGUINARIA CANADENSIS ROOT	15 [hp_X] in 1 mL
CLAVICEPS PURPUREA SCLEROTIUM (UNII: 01G9XEA93N) (CLAVICEPS PURPUREA SCLEROTIUM - UNII:01G9XEA93N)	CLAVICEPS PURPUREA SCLEROTIUM	15 [hp_X] in 1 mL
VIPERA BERUS VENOM (UNII: 0ORO6NCA4M) (VIPERA BERUS VENOM - UNII:0ORO6NCA4M)	VIPERA BERUS VENOM	15 [hp_X] in 1 mL
APIS MELLIFERA (UNII: 7S82P3R43Z) (APIS MELLIFERA - UNII:7S82P3R43Z)	APIS MELLIFERA	6 [hp_X] in 1 mL
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	6 [hp_X] in 1 mL
THUJA OCCIDENTALIS LEAFY TWIG (UNII: 1NT28V9397) (THUJA OCCIDENTALIS LEAFY TWIG - UNII:1NT28V9397)	THUJA OCCIDENTALIS LEAFY TWIG	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:55714-4798-1	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(55714-4798)

Revised: 12/2020

Newton Laboratories, Inc.