

MENOPAUSE- elaps corallinus, agnus, angelica sinensis radix, arsenicum alb., bryonia, cantharis, caulophyllum, cimicifuga, cinchona, crotalus horridus, damiana, glonoinum, helonias dioica, ignatia, kali carb., lachesis, naja, nux vom., phosphorus, pulsatilla, salix nigra, sanguinaria, sepia, echinacea, valeriana 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.

Menopause 4800L

INDICATIONS & USAGE SECTION

Formulated for associated symptoms such as hot flashes, decreased libido, insomnia, mood swings, discomfort and fatigue.

DOSAGE & ADMINISTRATION SECTION

Directions: Adults, take 6 drops by mouth one to four times daily or as directed by a health professional.

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Echinacea 11x, Valeriana officinalis 11x, Agnus castus 15x, Angelica sinensis radix 15x, Bryonia 15x, Cantharis 15x, Caulophyllum thalictroides 15x, Cimicifuga racemosa 15x, Cinchona officinalis 15x, Crotalus horridus 15x, Damiana 15x, Glonoinum 15x, Helonias dioica 15x, Ignatia amara 15x, Kali carbonicum 15x, Lachesis mutus 15x, Naja tripudians 15x, Phosphorus 15x, Pulsatilla 15x, Salix nigra 15x, Sanguinaria canadensis 15x, Sepia 15x, Arsenicum album 20x, Nux vomica 20x, Elaps corallinus 35x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as hot flashes, decreased libido, insomnia, mood swings, discomfort and fatigue.

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# 55714-4800-1

Menopause
 Formulated for associated symptoms such as hot flashes, decreased libido, insomnia, mood swings, discomfort and fatigue.

1 FL OZ (30 ML)

Dispensed by health professionals - not sold over-the-counter.
Directions: Adults, take 6 drops by mouth one to four times daily or as directed by a health professional.
Active Ingredients: Equal parts of Echinacea 11x, Valeriana 11x, Agnus 15x, Angelica sin. 15x, Bryonia 15x, Cantharis 15x, Caulophyllum 15x, Cimicifuga 15x, Cinchona 15x, Crotalus hor. 15x, Damiana 15x, Glonoinum 15x, Helonias 15x, Ignatia 15x, Kali carb. 15x, Lachesis 15x, Naja 15x, Phos. 15x, Pulsatilla 15x, Salix nig. 15x, Sanguinaria 15x, Sepia 15x, Arsenicum alb. 20x, Nux vom. 20x, Elaps 35x.
Inactive Ingredients: USP Purified water; USP Gluten-free, non-GMO, organic cane alcohol 20%.

Stock# R029 Lot#

MENOPAUSE

elaps corallinus, agnus, angelica sinensis radix, arsenicum alb., bryonia, cantharis, caulophyllum, cimicifuga, cinchona, crotalus horridus, damiana, glonoinum, helonias dioica, ignatia, kali carb., lachesis, naja, nux vom., phosphorus, pulsatilla, salix nigra, sanguinaria, sepia, echinacea, valeriana liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-4800
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CROTALUS HORRIDUS HORRIDUS VENOM (UNII: YHA2XLJ956) (CROTALUS HORRIDUS HORRIDUS VENOM - UNII:YHA2XLJ956)	CROTALUS HORRIDUS HORRIDUS VENOM	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
TURNERA DIFFUSA LEAFY TWIG (UNII: RQ2CFA7WWJ) (TURNERA DIFFUSA LEAFY TWIG - UNII:RQ2CFA7WWJ)	TURNERA DIFFUSA LEAFY TWIG	15 [hp_X] in 1 mL
NITRO GLYCERIN (UNII: G59M7S0WS3) (NITROGLYCERIN - UNII:G59M7S0WS3)	NITROGLYCERIN	15 [hp_X] in 1 mL

CHAMAELIRIUM LUTEUM ROOT (UNII: DQV54Y5H3U) (CHAMAELIRIUM LUTEUM ROOT - UNII:DQV54Y5H3U)	CHAMAELIRIUM LUTEUM ROOT	15 [hp_X] in 1 mL
POTASSIUM CARBONATE (UNII: BQN1B9B9HA) (CARBONATE ION - UNII:7UJQ5OPE7D)	POTASSIUM CARBONATE	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
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	20 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	15 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	15 [hp_X] in 1 mL
SALIX NIGRA BARK (UNII: QU52J3A5B3) (SALIX NIGRA BARK - UNII:QU52J3A5B3)	SALIX NIGRA BARK	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
SEPIA OFFICINALIS JUICE (UNII: QDL83WN8C2) (SEPIA OFFICINALIS JUICE - UNII:QDL83WN8C2)	SEPIA OFFICINALIS JUICE	15 [hp_X] in 1 mL
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	11 [hp_X] in 1 mL
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	11 [hp_X] in 1 mL
MICRURUS CORALLINUS VENOM (UNII: V0S6H36980) (MICRURUS CORALLINUS VENOM - UNII:V0S6H36980)	MICRURUS CORALLINUS VENOM	35 [hp_X] in 1 mL
CHASTE TREE FRUIT (UNII: 433OSF3U8A) (CHASTE TREE FRUIT - UNII:433OSF3U8A)	CHASTE TREE FRUIT	15 [hp_X] in 1 mL
ANGELICA SINENSIS ROOT (UNII: B66F4574UG) (ANGELICA SINENSIS ROOT - UNII:B66F4574UG)	ANGELICA SINENSIS ROOT	15 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	20 [hp_X] in 1 mL
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	15 [hp_X] in 1 mL
LYTTA VESICATORIA (UNII: 3Q034RO3BT) (LYTTA VESICATORIA - UNII:3Q034RO3BT)	LYTTA VESICATORIA	15 [hp_X] in 1 mL
CAULOPHYLLUM THALICTROIDES ROOT (UNII: JTJ6HH6YEH) (CAULOPHYLLUM THALICTROIDES ROOT - UNII:JTJ6HH6YEH)	CAULOPHYLLUM THALICTROIDES ROOT	15 [hp_X] in 1 mL
BLACK COHOSH (UNII: K73E24S6X9) (BLACK COHOSH - UNII:K73E24S6X9)	BLACK COHOSH	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

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-4800-1	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(55714-4800)

Revised: 12/2020

Newton Laboratories, Inc.