

ACNE - CYSTIC ACNE- echinacea, juglans regia, lappa major, taraxacum officinale, antimonium crudum, arsenicum album, aurum metallicum, berberis aquifolium, bovista, carbo vegetabilis, causticum, chelidonium majus, dulcamara, graphites, hepar sulphuris calcareum, hydrocotyle asiatica, kali bromatum, kali iodatum, ledum palustre, lycopodium clavatum, nux vomica, sulphur iodatum, zincum metallicum, silicea 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.

Acne 4790L

INDICATIONS & USAGE SECTION

Formulated for symptoms associated with acne such as boils, pimples, pustules, and sebaceous cysts.

DOSAGE & ADMINISTRATION SECTION

Directions: Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) one to four times a day or as directed by a health professional.

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Echinacea 6x, Juglans reg. 6x, Lappa 6x, Taraxacum 6x, Antimon. crud. 15x, Arsenicum alb. 15x, Aur. met. 15x, Berber. aqi. 15x, Bovista 15x, Carbo veg. 15x, Causticum 15x, Chelidonium maj. 15x, Dulcamara 15x, Graphites 15x, Hepar sulph. calc. 15x, Hydrocotyle 15x, Kali brom. 15x, Kali iod. 15x, Ledum 15x, Lycopodium 15x, Nux vom. 15x, Silicea 15x, Sulphur iod. 15x, Zinc. met. 15x.

OTC - PURPOSE SECTION

Formulated for symptoms associated with acne such as boils, pimples, pustules and sebaceous cysts.

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

newtonlabs.net ~ Questions? 800.448.7256
 Newton Laboratories, Inc. FDA Est# 1051203 • Conyers, GA 30013
 Label statements have not been reviewed by the FDA.

NEWTON homeopathics™ PRO

NDC# 55714-4790-1

**Acne~
Cystic Acne**

Formulated for symptoms associated with acne such as boils, pimples, pustules and sebaceous cysts.

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) one to four times daily or as directed by a health professional.
Active Ingredients: Equal parts of Echinacea 6x, Juglans reg. 6x, Lappa 6x, Taraxacum 6x, Antimon. crud. 15x, Arsenicum alb. 15x, Aur. met. 15x, Berber. aqui. 15x, Bovista 15x, Carbo veg. 15x, Causticum 15x, Chelidonium maj. 15x, Dulcamara 15x, Graphites 15x, Hepar sulph. calc. 15x, Hydrocotyle 15x, Kali brom. 15x, Kali iod. 15x, Ledum 15x, Lycopodium 15x, Nux vom. 15x, Silicea 15x, Sulphur iod. 15x, Zinc. met. 15x.
Inactive Ingredients: USP Purified water; USP Gluten-free, non-GMO, organic cane alcohol 20%.

Stock# R035 Lot#

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.

ACNE - CYSTIC ACNE

echinacea, juglans regia, lappa major, taraxacum officinale, antimonium crudum, arsenicum album, aurum metallicum, berberis aquifolium, bovista, carbo vegetabilis, causticum, chelidonium majus, dulcamara, graphites, hepar sulphuris calcareum, hydrocotyle asiatica, kali bromatum, kali iodatum, ledum palustre, lycopodium clavatum, nux vomica, sulphur iodatum, zincum metallicum, silicea liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-4790
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAUSTICUM (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)	CAUSTICUM	15 [hp_X] in 1 mL
CHELIDONIUM MAJUS (UNII: 7E889U5RNN) (CHELIDONIUM MAJUS - UNII:7E889U5RNN)	CHELIDONIUM MAJUS	15 [hp_X] in 1 mL
SOLANUM DULCAMARA WHOLE (UNII: G72JA9DHK5) (SOLANUM DULCAMARA WHOLE - UNII:G72JA9DHK5)	SOLANUM DULCAMARA WHOLE	15 [hp_X] in 1 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	15 [hp_X] in 1 mL
CENTELLA ASIATICA (UNII: 7M867G6T1U) (CENTELLA ASIATICA - UNII:7M867G6T1U)	CENTELLA ASIATICA	15 [hp_X] in 1 mL

ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	6 [hp_X] in 1 mL
JUGLANS REGIA WHOLE (UNII: 87EJ76IO83) (JUGLANS REGIA WHOLE - UNII:87EJ76IO83)	JUGLANS REGIA WHOLE	6 [hp_X] in 1 mL
GOLD (UNII: 79Y1949PYO) (GOLD - UNII:79Y1949PYO)	GOLD	15 [hp_X] in 1 mL
TARAXACUM OFFICINALE (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)	TARAXACUM OFFICINALE	6 [hp_X] in 1 mL
ANTIMONY TRISULFIDE (UNII: F79059A38U) (ANTIMONY TRISULFIDE - UNII:F79059A38U)	ANTIMONY TRISULFIDE	15 [hp_X] in 1 mL
BERBERIS AQUIFOLIUM WHOLE (UNII: J4WG1JVR05) (BERBERIS AQUIFOLIUM WHOLE - UNII:J4WG1JVR05)	BERBERIS AQUIFOLIUM WHOLE	15 [hp_X] in 1 mL
CALVATIA GIGANTEA WHOLE (UNII: BR6B7CG29T) (CALVATIA GIGANTEA WHOLE - UNII:BR6B7CG29T)	CALVATIA GIGANTEA WHOLE	15 [hp_X] in 1 mL
POTASSIUM BROMIDE (UNII: OSD78555ZM) (BROMIDE ION - UNII:952902IX06)	POTASSIUM BROMIDE	15 [hp_X] in 1 mL
ARCTIUM LAPPА WHOLE (UNII: 73070DU1LA) (ARCTIUM LAPPА WHOLE - UNII:73070DU1LA)	ARCTIUM LAPPА WHOLE	6 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	15 [hp_X] in 1 mL
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10) (ACTIVATED CHARCOAL - UNII:2P3VWU3H10)	ACTIVATED CHARCOAL	15 [hp_X] in 1 mL
GRAPHITE (UNII: 4QQN74LH4O) (GRAPHITE - UNII:4QQN74LH4O)	GRAPHITE	15 [hp_X] in 1 mL
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	15 [hp_X] in 1 mL
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	15 [hp_X] in 1 mL
LEDUM PALUSTRE WHOLE (UNII: 1N8KG72C5M) (LEDUM PALUSTRE WHOLE - UNII:1N8KG72C5M)	LEDUM PALUSTRE WHOLE	15 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	15 [hp_X] in 1 mL
SULFUR IODIDE (UNII: L6L8KA2AA0) (SULFUR IODIDE - UNII:L6L8KA2AA0)	SULFUR IODIDE	15 [hp_X] in 1 mL
LYCOPODIUM CLAVATUM WHOLE (UNII: 005ICF6L27) (LYCOPODIUM CLAVATUM WHOLE - UNII:005ICF6L27)	LYCOPODIUM CLAVATUM WHOLE	15 [hp_X] in 1 mL
STRYCHNOS NUX-VOMICA WHOLE (UNII: AB2NX17POS) (STRYCHNOS NUX-VOMICA WHOLE - UNII:AB2NX17POS)	STRYCHNOS NUX-VOMICA WHOLE	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:55714-4790-1	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
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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(55714-4790)

Revised: 12/2020

Newton Laboratories, Inc