

ACNE- antimon. crud., arsenicum alb., aur. met., berber. aqui., bovista, carbo veg., causticum, chelidonium majus, dulcamara, graphites, hepar sulph. calc., hydrocotyle, kali brom., kali iod., ledum, lycopodium, nux vom., silicea, sulphur iod., zinc. met., echinacea, juglans regia, lappa, taraxacum 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.

Acne 2385P

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

OTC - PREGNANCY OR BREAST FEEDING SECTION

If **pregnant or breast-feeding**, ask a doctor before use.

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.

QUESTIONS

newtonlabs.net - Questions ? 800 448-7256

Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 300123

INACTIVE INGREDIENT SECTION

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

DOSAGE & ADMINISTRATION SECTION

Directions: Ages 12 and up, take 6 pellets by mouth (ages 0 to 11, give 3 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.

OTC - PURPOSE SECTION

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

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. 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.

INDICATIONS & USAGE SECTION

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

PACKAGE LABEL

newtonhomeopathics.net ~ Questions? 800.448.7256
 Newton Laboratories, Inc. FDA Est #1051203 • Compens. GA 30013
Label statements have not been reviewed by the FDA.
WARNING: 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
 Since 1987

NDC#
 55714-2385-1

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

1 OZ (28 G)

Directions: Ages 12 and up, take 6 pellets by mouth (ages 0 to 11, give 3 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 Echinacea 6x, Juglans reg. 6x, Lappa 6x, Taraxacum 6x, Antimon. crud. 15x, Arsenicum alb. 15x, Aur. met. 15x, Berber. aqu. 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: Gluten-free, non-GMO, organic beet-derived sucrose (lactose-free) pellets.

Stock# N015 Lot#

ACNE

antimon. crud., arsenicum alb., aur. met., berber. aqu., bovista, carbo veg., causticum, chelidonium majus, dulcamara, graphites, hepar sulph. calc., hydrocotyle, kali brom., kali iod., ledum, lycopodium, nux vom., silicea, sulphur iod., zinc. met., echinacea, juglans regia, lappa, taraxacum pellet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2385
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ANTIMONY TRISULFIDE (UNII: F79059A38U) (ANTIMONY TRISULFIDE - UNII:F79059A38U)	ANTIMONY TRISULFIDE	15 [hp_X] in 1 g
ARSENIC CATION (3+) (UNII: C96613F5AV) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC CATION (3+)	15 [hp_X] in 1 g
GOLD (UNII: 79Y1949PYO) (GOLD - UNII:79Y1949PYO)	GOLD	15 [hp_X] in 1 g
MAHONIA AQUIFOLIUM ROOT BARK (UNII: VZJ9F3C3SB) (MAHONIA AQUIFOLIUM ROOT BARK - UNII:VZJ9F3C3SB)	MAHONIA AQUIFOLIUM ROOT BARK	15 [hp_X] in 1 g
GIANT PUFFBALL (UNII: I6839Y031A) (GIANT PUFFBALL - UNII:I6839Y031A)	GIANT PUFFBALL	15 [hp_X] in 1 g

ACTIVATED CHARCOAL (UNII: 2P3VWU3H10) (ACTIVATED CHARCOAL - UNII:2P3VWU3H10)	ACTIVATED CHARCOAL	15 [hp_X] in 1 g
CAUSTICUM (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)	CAUSTICUM	15 [hp_X] in 1 g
CHELIDONIUM MAJUS (UNII: 7E889U5RNN) (CHELIDONIUM MAJUS - UNII:7E889U5RNN)	CHELIDONIUM MAJUS	15 [hp_X] in 1 g
SOLANUM DULCAMARA TOP (UNII: KPS1B1162N) (SOLANUM DULCAMARA TOP - UNII:KPS1B1162N)	SOLANUM DULCAMARA TOP	15 [hp_X] in 1 g
GRAPHITE (UNII: 4QQN74LH4O) (GRAPHITE - UNII:4QQN74LH4O)	GRAPHITE	15 [hp_X] in 1 g
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	15 [hp_X] in 1 g
CENTELLA ASIATICA (UNII: 7M867G6T1U) (CENTELLA ASIATICA - UNII:7M867G6T1U)	CENTELLA ASIATICA	15 [hp_X] in 1 g
POTASSIUM BROMIDE (UNII: OSD78555ZM) (BROMIDE ION - UNII:952902IX06)	POTASSIUM BROMIDE	15 [hp_X] in 1 g
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	15 [hp_X] in 1 g
LEDUM PALUSTRE TWIG (UNII: 877L01IZ0P) (LEDUM PALUSTRE TWIG - UNII:877L01IZ0P)	LEDUM PALUSTRE TWIG	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
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	15 [hp_X] in 1 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	15 [hp_X] in 1 g
SULFUR IODIDE (UNII: L6L8KA2AA0) (SULFUR IODIDE - UNII:L6L8KA2AA0)	SULFUR IODIDE	15 [hp_X] in 1 g
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	15 [hp_X] in 1 g
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	6 [hp_X] in 1 g
ENGLISH WALNUT (UNII: 1V3SHR7QB7) (ENGLISH WALNUT - UNII:1V3SHR7QB7)	ENGLISH WALNUT	6 [hp_X] in 1 g
ARCTIUM LAPPAL ROOT (UNII: 597E9BI3Z3) (ARCTIUM LAPPAL ROOT - UNII:597E9BI3Z3)	ARCTIUM LAPPAL ROOT	6 [hp_X] in 1 g
TARAXACUM OFFICINALE (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)	TARAXACUM OFFICINALE	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:55714-2385-1	28 g in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/31/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/31/2018	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-2385)

Revised: 11/2020

Newton Laboratories, Inc.