

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 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

INDICATIONS & USAGE SECTION

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

DOSAGE & ADMINISTRATION SECTION

Directions: ORAL USE ONLY - SHAKE WELL. Ages 12 and up, take 6 drops orally (ages 0 to 11, give 3 drops) one to four times daily or as directed by a healthcare professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Antimon. crud. 15x, Arsenicum alb. 15x, Aur. met. 15x, Berber. aqui. 15x, Bovista 15x, Carbo veg. 15x, Causticum 15x, Chelidonium majus 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, Echinacea 3x, Juglans regia 3x, Lappa 3x, Taraxacum 3x.

OTC - PURPOSE SECTION

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

INACTIVE INGREDIENT SECTION

Inactive Ingredients: USP Purified Water; USP Gluten-free, non-GMO, organic cane dispensing alcohol 20%.

QUESTIONS

www.newtonlabs.net Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 30012

Questions? 1.800.448.7256

WARNINGS SECTION

Warning: Do not use if tamper - evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.

OTC - PREGNANCY OR BREAST FEEDING SECTION

Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

PACKAGE LABEL

www.newtonlabs.net
 Newton Laboratories, Inc., FDA Est# 1051203 • Conyers, GA 30012
Questions? 1.800.448.7256

Warnings: Do not use if tamper-evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.

NEWTON homeopathics
 Nurturing Naturally Since 1987™

NDC# 55714-2228-1

Acne

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

1 fl oz (29.57 ml)

Directions: ORAL USE ONLY - SHAKE WELL.
 Ages 12 and up, take 6 drops orally (ages 0 to 11, give 3 drops) one to four times daily or as directed by a healthcare professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

Active Ingredients: Antimon. crud. 15x, Arsenicum alb. 15x, Aur. met. 15x, Berber. aqui. 15x, Bovista 15x, Carbo veg. 15x, Causticum 15x, Chelidonium majus 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, Echinacea 3x, Juglans regia 3x, Lappa 3x, Taraxacum 3x.

Inactive Ingredients: USP Purified water; USP Gluten-free, non-GMO, organic cane dispensing alcohol 20%.

Stock# N015 Lot#

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 liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2228
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 mL
Arsenic Trioxide (UNII: S7V92P67HO) (Arsenic Cation (3+) - UNII:C96613F5AV)	Arsenic Trioxide	15 [hp_X] in 1 mL
Gold (UNII: 79Y1949PYO) (Gold - UNII:79Y1949PYO)	Gold	15 [hp_X] in 1 mL
Mahonia Aquifolium Root Bark (UNII: VZJ9F3C3SB) (Mahonia Aquifolium Root Bark - UNII:VZJ9F3C3SB)	Mahonia Aquifolium Root Bark	15 [hp_X] in 1 mL
Giant Puffball (UNII: I6839Y031A) (Giant Puffball - UNII:I6839Y031A)	Giant Puffball	15 [hp_X] in 1 mL
Activated Charcoal (UNII: 2B3VW1I3H1O) (Activated Charcoal - UNII:2B3VW1I3H1O)	Activated Charcoal	15 [hp_X]

Activated Charcoal (UNII: 2F3VW03110) (Activated Charcoal - UNII:2F3VW03110)	Activated Charcoal	in 1 mL
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 Top (UNII: KPS1B1162N) (Solanum Dulcamara Top - UNII:KPS1B1162N)	Solanum Dulcamara Top	15 [hp_X] in 1 mL
Graphite (UNII: 4QQN74LH4O) (Graphite - UNII:4QQN74LH4O)	Graphite	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
Potassium Bromide (UNII: OSD78555ZM) (Potassium Cation - UNII:295O53K152)	Potassium Bromide	15 [hp_X] in 1 mL
Potassium Iodide (UNII: 1C4QK22F9J) (Iodide Ion - UNII:09G4I6V86Q)	Potassium Iodide	15 [hp_X] in 1 mL
Ledum Palustre Twig (UNII: 877L01IZ0P) (Ledum Palustre Twig - UNII:877L01IZ0P)	Ledum Palustre Twig	15 [hp_X] in 1 mL
Lycopodium Clavatum Spore (UNII: C88X29Y479) (Lycopodium Clavatum Spore - UNII:C88X29Y479)	Lycopodium Clavatum Spore	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
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
Zinc (UNII: J41CSQ7QDS) (Zinc - UNII:J41CSQ7QDS)	Zinc	15 [hp_X] in 1 mL
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	3 [hp_X] in 1 mL
English Walnut (UNII: 1V3SHR7QB7) (English Walnut - UNII:1V3SHR7QB7)	English Walnut	3 [hp_X] in 1 mL
Arctium Lappa Root (UNII: 597E9BI3Z3) (Arctium Lappa Root - UNII:597E9BI3Z3)	Arctium Lappa Root	3 [hp_X] in 1 mL
Taraxacum Officinale (UNII: 39981FM375) (Taraxacum Officinale - UNII:39981FM375)	Taraxacum Officinale	3 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Alcohol (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2228-1	29.57 mL in 1 BOTTLE, GLASS		
2	NDC:55714-2228-2	59.14 mL in 1 BOTTLE, GLASS		
3	NDC:55714-2228-0	.5 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/01/2011	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-2228) , API MANUFACTURE(55714-2228)

Revised: 3/2011

Newton Laboratories, Inc.