

**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.*

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**Acne 2384L**

## **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 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 30013

## **INACTIVE INGREDIENT SECTION**

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

## **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 regia 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.

## **DOSAGE & ADMINISTRATION SECTION**

**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. Sensitive persons begin with 1 drop and gradually increase to full dose.

## INDICATIONS & USAGE SECTION

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

## PACKAGE LABEL

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

**NEWTON homeopathics™**  
 Since 1987

NDC#  
 55714-2384-1

**Acne**

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

**1 FL OZ (30 ML)**

**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. Sensitive persons begin with 1 drop 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:** USP Purified water; USP Gluten-free, non-GMO, organic cane alcohol 20%.

Stock# **N015** 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

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 liquid

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:55714-2384 |
| <b>Route of Administration</b> | ORAL           |                           |                |

### Active Ingredient/Active Moiety

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

|   |                           |                   |
|---|---------------------------|-------------------|
| <b>ACTIVATED CHARCOAL</b> (UNII: 2P3VWU3H10) (ACTIVATED CHARCOAL - UNII:2P3VWU3H10)               | ACTIVATED CHARCOAL        | 15 [hp_X] in 1 mL |
| <b>CAUSTICUM</b> (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)                                 | CAUSTICUM                 | 15 [hp_X] in 1 mL |
| <b>CHELIDONIUM MAJUS</b> (UNII: 7E889U5RNN) (CHELIDONIUM MAJUS - UNII:7E889U5RNN)                 | CHELIDONIUM MAJUS         | 15 [hp_X] in 1 mL |
| <b>SOLANUM DULCAMARA TOP</b> (UNII: KPS1B1162N) (SOLANUM DULCAMARA TOP - UNII:KPS1B1162N)         | SOLANUM DULCAMARA TOP     | 15 [hp_X] in 1 mL |
| <b>GRAPHITE</b> (UNII: 4QQN74LH4O) (GRAPHITE - UNII:4QQN74LH4O)                                   | GRAPHITE                  | 15 [hp_X] in 1 mL |
| <b>CALCIUM SULFIDE</b> (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)                     | CALCIUM SULFIDE           | 15 [hp_X] in 1 mL |
| <b>CENTELLA ASIATICA</b> (UNII: 7M867G6T1U) (CENTELLA ASIATICA - UNII:7M867G6T1U)                 | CENTELLA ASIATICA         | 15 [hp_X] in 1 mL |
| <b>POTASSIUM BROMIDE</b> (UNII: OSD78555ZM) (BROMIDE ION - UNII:952902IX06)                       | POTASSIUM BROMIDE         | 15 [hp_X] in 1 mL |
| <b>POTASSIUM IODIDE</b> (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)                         | IODIDE ION                | 15 [hp_X] in 1 mL |
| <b>LEDUM PALUSTRE TWIG</b> (UNII: 877L01IZ0P) (LEDUM PALUSTRE TWIG - UNII:877L01IZ0P)             | LEDUM PALUSTRE TWIG       | 15 [hp_X] in 1 mL |
| <b>LYCOPODIUM CLAVATUM SPORE</b> (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479) | LYCOPODIUM CLAVATUM SPORE | 15 [hp_X] in 1 mL |
| <b>STRYCHNOS NUX-VOMICA SEED</b> (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919) | STRYCHNOS NUX-VOMICA SEED | 15 [hp_X] in 1 mL |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)                     | SILICON DIOXIDE           | 15 [hp_X] in 1 mL |
| <b>SULFUR IODIDE</b> (UNII: L6L8KA2AA0) (SULFUR IODIDE - UNII:L6L8KA2AA0)                         | SULFUR IODIDE             | 15 [hp_X] in 1 mL |
| <b>ZINC</b> (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)   | ZINC                      | 15 [hp_X] in 1 mL |
| <b>ECHINACEA, UNSPECIFIED</b> (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)       | ECHINACEA, UNSPECIFIED    | 6 [hp_X] in 1 mL  |
| <b>ENGLISH WALNUT</b> (UNII: 1V3SHR7QB7) (ENGLISH WALNUT - UNII:1V3SHR7QB7)                       | ENGLISH WALNUT            | 6 [hp_X] in 1 mL  |
| <b>ARCTIUM LAPPAL ROOT</b> (UNII: 597E9B13Z3) (ARCTIUM LAPPAL ROOT - UNII:597E9B13Z3)             | ARCTIUM LAPPAL ROOT       | 6 [hp_X] in 1 mL  |
| <b>TARAXACUM OFFICINALE</b> (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)           | TARAXACUM OFFICINALE      | 6 [hp_X] in 1 mL  |

### Inactive Ingredients

| Ingredient Name                   | Strength |
|-----------------------------------|----------|
| <b>ALCOHOL</b> (UNII: 3K9958V90M) |          |
| <b>WATER</b> (UNII: 059QF0K00R)   |          |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:55714-2384-0 | 0.5 mL in 1 BOTTLE, GLASS; Type 8: Possible Combination Based on Cross Labeling of Separate Products (Temporary Type) | 10/31/2018           | 01/31/2019         |
| 2 | NDC:55714-2384-1 | 30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product   | 10/31/2018           |                    |
| 3 | NDC:55714-2384-2 | 50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product   | 10/31/2018           | 01/31/2019         |

## 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(55714-2384) |

Revised: 11/2020

Newton Laboratories, Inc.