

**TINNITUS- aconitum nap., baryta carb., baryta mur., capsicum, causticum, chenopodium anthelminticum, chininum sulphuricum, cinchona, glonoinum, graphites, hydrastis, kali bic., kali mur., lycopodium, phosphorus, pulsatilla, salicylicum ac., tabacum, thiosinaminum, viola odorata 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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**Tinnitus 4808L**

## **INDICATIONS & USAGE SECTION**

Formulated for associated symptoms such as ringing, buzzing, echoing, pressure, pain, throbbing and sensitivity to noise.

## **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 Hydrastis canadensis 11x, Aconitum napellus 15x, Baryta carbonica 15x, Baryta muriatica 15x, Capsicum annuum 15x, Causticum 15x, Chenopodium anthelminticum 15x, Chininum sulphuricum 15x, Cinchona officinalis 15x, Glonoinum 15x, Graphites 15x, Hydrastis canadensis 15x, Kali bichromicum 15x, Kali muriaticum 15x, Lycopodium clavatum 15x, Phosphorus 15x, Pulsatilla 15x, Salicylicum acidum 15x, Tabacum 15x, Thiosinaminum 15x, Viola odorata 15x.

## **OTC - PURPOSE SECTION**

Formulated for associated symptoms such as ringing, buzzing, echoing, pressure, pain, throbbing and sensitivity to noise.

## **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**

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

**OTC - KEEP OUT OF REACH OF CHILDREN SECTION**

**WARNINGS:** 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#  
55714-4808-1

**Tinnitus**

Formulated for associated symptoms such as ringing, buzzing, echoing, pressure, pain, throbbing and sensitivity to noise.

**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 6 to 11, give 3 drops) as needed or as directed by a health professional.

**Active Ingredients:** Equal parts of Hydrastis 11x, Aconitum nap. 15x, Baryta carb. 15x, Baryta mur. 15x, Capsicum 15x, Causticum 15x, Chenopodium anth. 15x, Chininum sulph. 15x, Cinchona 15x, Glonoinum 15x, Graphites 15x, Hydrastis 15x, Kali bic. 15x, Kali mur. 15x, Lycopodium 15x, Phos. 15x, Pulsatilla 15x, Salicylicum ac. 15x, Tabacum 15x, Thiosinaminum 15x, Viola od. 15x.

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

**Stock# R103 Lot#**

## TINNITUS

aconitum nap., baryta carb., baryta mur., capsicum, causticum, chenopodium anthelminticum, chininum sulphuricum, cinchona, glonoinum, graphites, hydrastis, kali bic., kali mur., lycopodium, phosphorus, pulsatilla, salicylicum ac., tabacum, thiosinaminum, viola odorata liquid

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:55714-4808 |
| <b>Route of Administration</b> | ORAL           |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name                                                                       | Basis of Strength         | Strength          |
|---------------------------------------------------------------------------------------|---------------------------|-------------------|
| <b>ACONITUM NAPELLUS</b> (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)     | ACONITUM NAPELLUS         | 15 [hp_X] in 1 mL |
| <b>BARIUM CARBONATE</b> (UNII: 6P669D8HQ8) (BARIUM CATION - UNII:V645272HLN)          | BARIUM CARBONATE          | 15 [hp_X] in 1 mL |
| <b>BARIUM CHLORIDE DIHYDRATE</b> (UNII: EL5GJ3U77E) (BARIUM CATION - UNII:V645272HLN) | BARIUM CHLORIDE DIHYDRATE | 15 [hp_X] in 1 mL |
| <b>CAPSICUM</b> (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)                       | CAPSICUM                  | 15 [hp_X] in 1 mL |

|                                                                                            |                              |                      |
|--------------------------------------------------------------------------------------------|------------------------------|----------------------|
| CAUSTICUM (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)                                 | CAUSTICUM                    | 15 [hp_X]<br>in 1 mL |
| DYSPHANIA AMBROSIOIDES (UNII: 4H5RSU087I) (DYSPHANIA AMBROSIOIDES - UNII:4H5RSU087I)       | DYSPHANIA<br>AMBROSIOIDES    | 15 [hp_X]<br>in 1 mL |
| QUININE SULFATE (UNII: KF7Z0E0Q2B) (QUININE - UNII:A7V27PHC7A)                             | QUININE SULFATE              | 15 [hp_X]<br>in 1 mL |
| CINCHONA OFFICINALIS BARK (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB) | CINCHONA OFFICINALIS<br>BARK | 15 [hp_X]<br>in 1 mL |
| NITROGLYCERIN (UNII: G59M7S0WS3) (NITROGLYCERIN - UNII:G59M7S0WS3)                         | NITROGLYCERIN                | 15 [hp_X]<br>in 1 mL |
| GRAPHITE (UNII: 4QQN74LH4O) (GRAPHITE - UNII:4QQN74LH4O)                                   | GRAPHITE                     | 15 [hp_X]<br>in 1 mL |
| GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)                               | GOLDENSEAL                   | 15 [hp_X]<br>in 1 mL |
| POTASSIUM DICHROMATE (UNII: T4423S18FM) (DICHROMATE ION - UNII:9LKY4BFN2V)                 | POTASSIUM<br>DICHROMATE      | 15 [hp_X]<br>in 1 mL |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)                 | POTASSIUM CHLORIDE           | 15 [hp_X]<br>in 1 mL |
| LYCOPodium CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPodium CLAVATUM SPORE - UNII:C88X29Y479) | LYCOPodium<br>CLAVATUM SPORE | 15 [hp_X]<br>in 1 mL |
| PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)                               | PHOSPHORUS                   | 15 [hp_X]<br>in 1 mL |
| ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)               | ANEMONE PULSATILLA           | 15 [hp_X]<br>in 1 mL |
| SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)                       | SALICYLIC ACID               | 15 [hp_X]<br>in 1 mL |
| TOBACCO LEAF (UNII: 6YR2608RSU) (TOBACCO LEAF - UNII:6YR2608RSU)                           | TOBACCO LEAF                 | 15 [hp_X]<br>in 1 mL |
| ALLYLTHIOUREA (UNII: 706IDJ14B7) (ALLYLTHIOUREA - UNII:706IDJ14B7)                         | ALLYLTHIOUREA                | 15 [hp_X]<br>in 1 mL |
| VIOLA ODORATA (UNII: AET12U8B74) (VIOLA ODORATA - UNII:AET12U8B74)                         | VIOLA ODORATA                | 15 [hp_X]<br>in 1 mL |

Inactive Ingredients

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

Packaging

| # | Item Code        | Package Description                                         | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:55714-4808-1 | 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(55714-4808) |

Revised: 12/2020

Newton Laboratories, Inc.