

**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.

Tinnitus 4857L

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

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Hydrastis canadensis 11x, Aconitum napellus 20x, Baryta carbonica 20x, Baryta muriatica 20x, Capsicum annuum 20x, Causticum 20x, Chenopodium anthelminticum 20x, Chininum sulphuricum 20x, Cinchona officinalis 20x, Glonoinum 20x, Graphites 20x, Hydrastis canadensis 20x, Kali bichromicum 20x, Kali muriaticum 20x, Lycopodium clavatum 20x, Phosphorus 20x, Pulsatilla 20x, Salicylicum acidum 20x, Tabacum 20x, Thiosinaminum 20x, Viola odorata 20x.

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 • Conners, 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#
55714-4857-1

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. 20x, Baryta carb. 20x, Baryta mur. 20x, Capsicum 20x, Causticum 20x, Chenopodium anth. 20x, Chininum sulph. 20x, Cinchona 20x, Glonoinum 20x, Graphites 20x, Hydrastis 20x, Kali bic. 20x, Kali mur. 20x, Lycopodium 20x, Phos. 20x, Pulsatilla 20x, Salicylicum ac. 20x, Tabacum 20x, Thiosinaminum 20x, Viola od. 20x.
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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-4857
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	20 [hp_X] in 1 mL
BARIUM CARBONATE (UNII: 6P669D8HQ8) (BARIUM CATION - UNII:V645272HLN)	BARIUM CARBONATE	20 [hp_X] in 1 mL
BARIUM CHLORIDE DIHYDRATE (UNII: EL5GJ3U77E) (BARIUM CATION - UNII:V645272HLN)	BARIUM CHLORIDE DIHYDRATE	20 [hp_X] in 1 mL
CAPSICUM (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)	CAPSICUM	20 [hp_X] in 1 mL
CAUSTICUM (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)	CAUSTICUM	20 [hp_X] in 1 mL
DYSPHANIA AMBROSIODES (UNII: 4H5RSU087I) (DYSPHANIA AMBROSIODES - UNII:4H5RSU087I)	DYSPHANIA AMBROSIODES	20 [hp_X] in 1 mL
QUININE SULFATE (UNII: KF7Z0E0Q2B) (QUININE - UNII:A7V27PHC7A)	QUININE SULFATE	20 [hp_X] in 1 mL
CINCHONA OFFICINALIS BARK (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB)	CINCHONA OFFICINALIS BARK	20 [hp_X] in 1 mL
NITROGLYCERIN (UNII: G59M7S0WS3) (NITROGLYCERIN - UNII:G59M7S0WS3)	NITROGLYCERIN	20 [hp_X] in 1 mL
GRAPHITE (UNII: 4QQN74LH4O) (GRAPHITE - UNII:4QQN74LH4O)	GRAPHITE	20 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	20 [hp_X] in 1 mL
POTASSIUM DICHROMATE (UNII: T4423S18FM) (DICHROMATE ION - UNII:9LKY4BFN2V)	POTASSIUM DICHROMATE	20 [hp_X] in 1 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	20 [hp_X] in 1 mL
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	20 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	20 [hp_X] in 1 mL
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	20 [hp_X] in 1 mL
TOBACCO LEAF (UNII: 6YR2608RSU) (TOBACCO LEAF - UNII:6YR2608RSU)	TOBACCO LEAF	20 [hp_X] in 1 mL
ALLYLTHIOUREA (UNII: 706IDJ14B7) (ALLYLTHIOUREA - UNII:706IDJ14B7)	ALLYLTHIOUREA	20 [hp_X] in 1 mL
VIOLA ODORATA (UNII: AET12U8B74) (VIOLA ODORATA - UNII:AET12U8B74)	VIOLA ODORATA	20 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	20 [hp_X] 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:55714-4857-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	01/31/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/31/2024	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-4857)

Revised: 1/2024

Newton Laboratories, Inc.