

**EAR WAX BUILD-UP- elaps corallinus, alumina, carbo veg., causticum, conium, graphites, kali bic.,kali mur., lachesis, lycopodium, petroleum, pulsatilla, sabadilla, sepia, silicea, spongia, verbascum, 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.

EarWa 2428L

INDICATIONS & USAGE SECTION

Formulated for associated symptoms such as dryness, itching, hearing difficulties and excess wax accumulation.

DOSAGE & ADMINISTRATION SECTION

Directions: Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) as needed or as directed by a health professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Alumina 15x, Carbo veg. 15x, Causticum 15x, Conium 15x, Graphites 15x, Kali bic. 15x, Kali mur. 15x, Lachesis 15x, Lycopodium 15x, Petroleum 15x, Pulsatilla 15x, Sabadilla 15x, Sepia 15x, Silicea 15x, Spongia 15x, Verbascum 15x, Viola odorata 15x, Elaps 30x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as dryness, itching, hearing difficulties and excess wax accumulation.

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 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

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

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

PACKAGE LABEL

newtonlabs.net ~ Questions? 800.448.7256
 Newton Laboratories, Inc. FDA Est #1051203 • Compens. 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™
 Since 1987

NDC# 55714-2428-1

Ear Wax Build-Up

Formulated for associated symptoms such as dryness, itching, hearing difficulties and excess wax accumulation.

1 FL OZ (30 ML)

Directions: Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) as needed or as directed by a health professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

Active Ingredients: Equal parts of Alumina 15x, Carbo veg. 15x, Causticum 15x, Conium 15x, Graphites 15x, Kali bic. 15x, Kali mur. 15x, Lachesis 15x, Lycopodium 15x, Petroleum 15x, Pulsatilla 15x, Sabadilla 15x, Sepia 15x, Silicea 15x, Spongia 15x, Verbasum 15x, Viola od. 15x, Elaps 30x.

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

Stock# N072 Lot#

EAR WAX BUILD-UP

elaps corallinus, alumina, carbo veg., causticum, conium, graphites, kali bic.,kali mur., lachesis, lycopodium, petroleum, pulsatilla, sabadilla, sepia, silicea, spongia, verbasum, viola odorata liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2428
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICRURUS CORALLINUS VENOM (UNII: V0S6H36980) (MICRURUS CORALLINUS VENOM - UNII:V0S6H36980)	MICRURUS CORALLINUS VENOM	30 [hp_X] in 1 mL
ALUMINUM O XIDE (UNII: LM26O6933) (ALUMINUM OXIDE - UNII:LM26O6933)	ALUMINUM OXIDE	15 [hp_X] in 1 mL
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10) (ACTIVATED CHARCOAL - UNII:2P3VWU3H10)	ACTIVATED CHARCOAL	15 [hp_X] in 1 mL
CAUSTICUM (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)	CAUSTICUM	15 [hp_X] in 1 mL
CONIUM MACULATUM FLOWERING TOP (UNII: Q28R5GF371) (CONIUM MACULATUM FLOWERING TOP - UNII:Q28R5GF371)	CONIUM MACULATUM FLOWERING TOP	15 [hp_X] in 1 mL
GRAPHITE (UNII: 4QQN74LH4O) (GRAPHITE - UNII:4QQN74LH4O)	GRAPHITE	15 [hp_X] in 1 mL
POTASSIUM DICHROMATE (UNII: T4423S18FM) (DICHROMATE ION - UNII:9LKY4BFN2V)	POTASSIUM DICHROMATE	15 [hp_X] in 1 mL

POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	15 [hp_X] in 1 mL
LACHESIS MUTA VENOM (UNII: VSW71SS07I) (LACHESIS MUTA VENOM - UNII:VSW71SS07I)	LACHESIS MUTA VENOM	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
LIQUID PETROLEUM (UNII: 6ZAE7X688J) (LIQUID PETROLEUM - UNII:6ZAE7X688J)	LIQUID PETROLEUM	15 [hp_X] in 1 mL
PULSATILLA VULGARIS (UNII: I76KB35JEV) (PULSATILLA VULGARIS - UNII:I76KB35JEV)	PULSATILLA VULGARIS	15 [hp_X] in 1 mL
SCHOENOCAULON OFFICINALE SEED (UNII: 6NAF1689IO) (SCHOENOCAULON OFFICINALE SEED - UNII:6NAF1689IO)	SCHOENOCAULON OFFICINALE SEED	15 [hp_X] in 1 mL
SEPIA OFFICINALIS JUICE (UNII: QDL83WN8C2) (SEPIA OFFICINALIS JUICE - UNII:QDL83WN8C2)	SEPIA OFFICINALIS JUICE	15 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	15 [hp_X] in 1 mL
SPONGIA OFFICINALIS SKELETON, ROASTED (UNII: 1PIP394IID) (SPONGIA OFFICINALIS SKELETON, ROASTED - UNII:1PIP394IID)	SPONGIA OFFICINALIS SKELETON, ROASTED	15 [hp_X] in 1 mL
VERBASCUM THAPSUS (UNII: C9TD27U172) (VERBASCUM THAPSUS - UNII:C9TD27U172)	VERBASCUM THAPSUS	15 [hp_X] in 1 mL
VIOLA ODORATA (UNII: AET12U8B74) (VIOLA ODORATA - UNII:AET12U8B74)	VIOLA ODORATA	15 [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:55714-2428-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	01/31/2019	
2	NDC:55714-2428-2	50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	01/31/2019	08/01/2019
3	NDC:55714-2428-0	15 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	01/31/2019	08/01/2019

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/31/2019	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 1/2020

Newton Laboratories, Inc.