

EAR CARE- echinacea, hydrastis canadensis, apis mellifica, arsenicum album, belladonna, bryonia, capsicum annuum, causticum, cinchona officinalis, conium maculatum, dulcamara, ferrum phosphoricum, hepar sulphuris calcareum, kali sulphuricum, lycopodium clavatum, mercurius vivus, mezereum, phosphorus, plantago major, pulsatilla, silicea, verbascum thapsus, tellurium metallicum, influenzinum 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.

EarCa 1537L

INDICATIONS AND USAGE SECTION

Formulated for associated symptoms such as redness, pain, congestion, hearing difficulty, inflammation and irritability.

DOSAGE & ADMINISTRATION SECTION

Directions: Children, ages 0 to 11, give 3 drops by mouth (ages 12 and up, give 6 drops) one to four times daily or as directed by a health professional. Sensitive person begin with 1 drop and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Echinacea 6x, Hydrastis canadensis 6x, Apis mellifica 15x, Arsenicum album 15x, Belladonna 15x, Bryonia 15x, Capsicum annuum 15x, Causticum 15x, Cinchona officinalis 15x, Conium maculatum 15x, Dulcamara 15x, Ferrum phosphoricum 15x, Hepar sulphuris calcareum 15x, Kali sulphuricum 15x, Lycopodium clavatum 15x, Mercurius vivus 15x, Mezereum 15x, Phosphorus 15x, Plantago major 15x, Pulsatilla 15x, Silicea 15x, Tellurium metallicum 16x, Verbascum thapsus 15x, Influenzinum 30x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as redness, pain, congestion, hearing difficulty, inflammation and irritability.

INACTIVE INGREDIENT SECTION

USP Purified water; USP Gluten-free, non-GMO, organic cane alcohol 20%

QUESTIONS SECTION

newtonlabs.net – Questions? 800.448.7256

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

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 Kids

NDC# 55714-1537-1

Ear Care

Formulated for associated symptoms such as redness, pain, congestion, hearing difficulty, inflammation and irritability.

1 FL OZ (30 ML)

Directions: Children, ages 0 to 11, give 3 drops by mouth (ages 12 and up, give 6 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, Hydrastis 6x, Apis mel. 15x, Arsenicum alb. 15x, Belladonna 15x, Bryonia 15x, Capsicum 15x, Causticum 15x, Cinchona 15x, Conium 15x, Dulcamara 15x, Ferrum phos. 15x, Hepar sulph. calc. 15x, Kali sulph. 15x, Lycopodium 15x, Merc. viv. 15x, Mezereum 15x, Phos. 15x, Plantago 15x, Pulsatilla 15x, Silicea 15x, Verbascum 15x, Tellurium 16x, Influenzinum 30x.

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

Stock# F006 Lot#

EAR CARE

echinacea, hydrastis canadensis, apis mellifica, arsenicum album, belladonna, bryonia, capsicum annuum, causticum, cinchona officinalis, conium maculatum, dulcamara, ferrum phosphoricum, hepar sulphuris calcareum, kali sulphuricum, lycopodium clavatum, mercurius vivus, mezereum, phosphorus, plantago major, pulsatilla, silicea, verbascum thapsus, tellurium metallicum, influenzazinum liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-1537
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
INFLUENZA B VIRUS (UNII: 1314JZ2X6W) (INFLUENZA B VIRUS - UNII:1314JZ2X6W)		INFLUENZA B VIRUS	30 [hp_X] in 1 mL
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)		ECHINACEA, UNSPECIFIED	6 [hp_X] in 1 mL
FERROSFERRIC PHOSPHATE (UNII: 91GQH8I5F7) (FERROSFERRIC PHOSPHATE - UNII:91GQH8I5F7)		FERROSFERRIC PHOSPHATE	15 [hp_X] in 1 mL
APIS MELLIFERA (UNII: 7S82P3R43Z) (APIS MELLIFERA - UNII:7S82P3R43Z)		APIS MELLIFERA	15 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)		ARSENIC TRIOXIDE	15 [hp_X] in 1 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)		ATROPA BELLADONNA	15 [hp_X] in 1 mL
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)		BRYONIA ALBA ROOT	15 [hp_X] in 1 mL
CAPSICUM (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)		CAPSICUM	15 [hp_X] in 1 mL
CAUSTICUM (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)		CAUSTICUM	15 [hp_X] in 1 mL
CINCHONA OFFICINALIS BARK (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB)		CINCHONA OFFICINALIS BARK	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
SOLANUM DULCAMARA TOP (UNII: KPS1B1162N) (SOLANUM DULCAMARA TOP - UNII:KPS1B1162N)		SOLANUM DULCAMARA TOP	15 [hp_X] in 1 mL
POTASSIUM SULFATE (UNII: 1K573LC5TV) (POTASSIUM CATION - UNII:295O53K152)		POTASSIUM SULFATE	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
MERCURY (UNII: FXS1BY2PGL) (MERCURY - UNII:FXS1BY2PGL)		MERCURY	15 [hp_X] in 1 mL
DAPHNE MEZEREUM BARK (UNII: X2N6E405GV) (DAPHNE MEZEREUM BARK - UNII:X2N6E405GV)		DAPHNE MEZEREUM BARK	15 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)		PHOSPHORUS	15 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)		SILICON DIOXIDE	15 [hp_X] in 1 mL
PLANTAGO MAJOR (UNII: W2469WNO6U) (PLANTAGO MAJOR - UNII:W2469WNO6U)		PLANTAGO MAJOR	15 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)		ANEMONE PULSATILLA	15 [hp_X] in 1 mL
TELLURIUM (UNII: NQA0O090ZJ) (TELLURIUM - UNII:NQA0O090ZJ)		TELLURIUM	16 [hp_X] in 1 mL
VERBASCUM THAPSUS (UNII: C9TD27U172) (VERBASCUM THAPSUS - UNII:C9TD27U172)		VERBASCUM THAPSUS	15 [hp_X] in 1 mL
INFLUENZA A VIRUS (UNII: R9HH0NDE2E) (INFLUENZA A VIRUS - UNII:R9HH0NDE2E)		INFLUENZA A VIRUS	30 [hp_X] in 1 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)		CALCIUM SULFIDE	15 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)		GOLDENSEAL	6 [hp_X] in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-1537-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	03/07/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/07/2022	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-1537)

Revised: 3/2022

Newton Laboratories, Inc.