

EAR CARE - influenzzinum, tellurium metallicum, apis mel., arsenicum alb., belladonna, bryonia, capsicum, causticum, cinchona, conium, dulcamara, ferrum phosphoricum, hepar sulph. calc., kali sulph., ycopodium, merc. viv., mezereum, phosphorus, plantago, pulsatilla, silicea, verbasum, echinacea, hydrastis 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.

Ear Care

INDICATIONS & USAGE SECTION

Ear Care Formulated for symptoms associated with ear conditions such as redness, pain, congestion, hearing difficulty, inflammation and irritability.

DOSAGE & ADMINISTRATION SECTION

Directions: ORAL USE ONLY - SHAKE WELL. Children, ages 0 to 11, give 3 drops orally (ages 12 and up, give 6 drops) one to four times daily or as directed by a healthcare professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Influenzzinum 30x, Tellurium metallicum 15x, Apis mel. 10x, Arsenicum alb. 10x, Belladonna 10x, Bryonia 10x, Capsicum 10x, Causticum 10x, Cinchona 10x, Conium 10x, Dulcamara 10x, Ferrum phosphoricum 10x, Hepar sulph. calc. 10x, Kali sulph. 10x, Lycopodium 10x, Merc. viv. 10x, Mezereum 10x, Phosphorus 10x, Plantago 10x, Pulsatilla 10x, Silicea 10x, Verbasum 10x, Echinacea 3x, Hydrastis 3x.

OTC - PURPOSE SECTION

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

INACTIVE INGREDIENT SECTION

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

QUESTIONS SECTION

www.newtonlabs.net Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 30012
Questions? 1.800.448.7256

WARNINGS SECTION

Warning: Do not use if tamper - evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.

OTC - PREGNANCY OR BREAST FEEDING SECTION

Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

PACKAGE LABEL

www.newtonlabs.net
 Newton Laboratories, Inc. FDA Est# 1051203 • Conway, GA 30012
Questions? 1.800.448.7256
 Warning: Do not use if tamper-evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.

NEWTON
homeopathics
for Kids
 Nurturing Naturally Since 1987™

NDC#
 55714-1504-1

**Ear
 Care**

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

1 fl oz (29.57 ml)

Directions: ORAL USE ONLY - SHAKE WELL.
 Children, ages 0 to 11, give 3 drops orally (ages 12 and up, give 6 drops) one to four times daily or as directed by a healthcare professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

Active Ingredients: Influenzinum 30x, Tellurium metallicum 15x, Apis mel. 10x, Arsenicum alb. 10x, Belladonna 10x, Bryonia 10x, Capsicum 10x, Causticum 10x, Cinchona 10x, Conium 10x, Dulcamara 10x, Ferrum phosphoricum 10x, Hepar sulph. calc. 10x, Kali sulph. 10x, Lycopodium 10x, Merc. viv. 10x, Mezereum 10x, Phosphorus 10x, Plantago 10x, Pulsatilla 10x, Silicea 10x, Verbasum 10x, Echinacea 3x, Hydrastis 3x.

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

Stock# **F006** Lot#

EAR CARE

influenzinum, tellurium metallicum, apis mel., arsenicum alb., belladonna, bryonia, capsicum, austicum, cinchona, conium, dulcamara, ferrum phosphoricum, hepar sulph. calc., kali sulph., ycopodium, merc. viv., mezereum, phosphorus, plantago, pulsatilla, silicea, verbasum, echinacea, hydrastis liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-1504
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Influenza A Virus (UNII: R9HH0NDE2E) (Influenza A Virus - UNII:R9HH0NDE2E)	Influenza A Virus	30 [hp_X] in 1 mL
Tellurium (UNII: NQA0O090ZJ) (Tellurium - UNII:NQA0O090ZJ)	Tellurium	15 [hp_X] in 1 mL
Apis Mellifera (UNII: 7S82P3R43Z) (Apis Mellifera - UNII:7S82P3R43Z)	Apis Mellifera	10 [hp_X] in 1 mL
Arsenic Trioxide (UNII: S7V92P67HO) (Arsenic Cation (3+) - UNII:C96613F5AV)	Arsenic Trioxide	10 [hp_X] in 1 mL
Atropa Belladonna (UNII: WQZ3G9PF0H) (Atropa Belladonna - UNII:WQZ3G9PF0H)	Atropa Belladonna	10 [hp_X] in 1 mL

Bryonia Alba Root (UNII: T7J046YI2B) (Bryonia Alba Root - UNII:T7J046YI2B)	Bryonia Alba Root	10 [hp_X] in 1 mL
Capsicum (UNII: 00UK7646FG) (Capsicum - UNII:00UK7646FG)	Capsicum	10 [hp_X] in 1 mL
Causticum (UNII: DD5FO1WKFU) (Causticum - UNII:DD5FO1WKFU)	Causticum	10 [hp_X] in 1 mL
Cinchona Officinalis Bark (UNII: S003A158SB) (Cinchona Officinalis Bark - UNII:S003A158SB)	Cinchona Officinalis Bark	10 [hp_X] in 1 mL
Conium Maculatum Flowering Top (UNII: Q28R5GF371) (Conium Maculatum Flowering Top - UNII:Q28R5GF371)	Conium Maculatum Flowering Top	10 [hp_X] in 1 mL
Solanum Dulcamara Top (UNII: KPS1B1162N) (Solanum Dulcamara Top - UNII:KPS1B1162N)	Solanum Dulcamara Top	10 [hp_X] in 1 mL
Ferrosoferric Phosphate (UNII: 91GQH8I5F7) (Ferrosoferric Phosphate - UNII:91GQH8I5F7)	Ferrosoferric Phosphate	10 [hp_X] in 1 mL
Calcium Sulfide (UNII: 1MBW07J51Q) (Calcium Sulfide - UNII:1MBW07J51Q)	Calcium Sulfide	10 [hp_X] in 1 mL
Potassium Sulfate (UNII: 1K573LC5TV) (Sulfate Ion - UNII:7IS9N8KPMG)	Potassium Sulfate	10 [hp_X] in 1 mL
Lycopodium Clavatum Spore (UNII: C88X29Y479) (Lycopodium Clavatum Spore - UNII:C88X29Y479)	Lycopodium Clavatum Spore	10 [hp_X] in 1 mL
Mercury (UNII: FXS1BY2PGL) (Mercury - UNII:FXS1BY2PGL)	Mercury	10 [hp_X] in 1 mL
Daphne Mezereum Bark (UNII: X2N6E405GV) (Daphne Mezereum Bark - UNII:X2N6E405GV)	Daphne Mezereum Bark	10 [hp_X] in 1 mL
Phosphorus (UNII: 27YLU75U4W) (Phosphorus - UNII:27YLU75U4W)	Phosphorus	10 [hp_X] in 1 mL
Plantago Major (UNII: W2469WNO6U) (Plantago Major - UNII:W2469WNO6U)	Plantago Major	10 [hp_X] in 1 mL
Pulsatilla Vulgaris (UNII: I76KB35JEV) (Pulsatilla Vulgaris - UNII:I76KB35JEV)	Pulsatilla Vulgaris	10 [hp_X] in 1 mL
Silicon Dioxide (UNII: ETJ7Z6XBU4) (Silicon Dioxide - UNII:ETJ7Z6XBU4)	Silicon Dioxide	10 [hp_X] in 1 mL
Verbascum Thapsus (UNII: C9TD27U172) (Verbascum Thapsus - UNII:C9TD27U172)	Verbascum Thapsus	10 [hp_X] in 1 mL
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	3 [hp_X] in 1 mL
Goldenseal (UNII: ZW3Z11D0JV) (Goldenseal - UNII:ZW3Z11D0JV)	Goldenseal	3 [hp_X] in 1 mL
Influenza B Virus (UNII: 1314JZ2X6W) (Influenza B Virus - UNII:1314JZ2X6W)	Influenza B Virus	30 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Alcohol (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-1504-1	29.57 mL in 1 BOTTLE, GLASS		
2	NDC:55714-1504-2	59.14 mL in 1 BOTTLE, GLASS		
3	NDC:55714-1504-0	.5 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/01/2011	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-1504)

Revised: 3/2011

Newton Laboratories, Inc.