

**EAR CARE- apis mel., arsenicum alb., belladonna, bromium, bryonia, capsicum, chelidonium majus, cinchona, ferrum phosphoricum, graphites, lycopodium, mancinella, merc. dulc., mezereum, nux vom., phosphorus, plantago, pulsatilla, rhus toxicodendron, sepia, verbas cum, viola tric., echinacea liquid
Newton Laboratories, Inc.**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Ear Care

INDICATIONS & USAGE SECTION

Formulated for associated symptoms such as discomfort, itching, irritation, inflammation and swelling.

DOSAGE & ADMINISTRATION SECTION

Directions: Pets, under 50 lbs., give 3 drops by mouth (50 to 500 lbs. - 6 drops, over 500 lbs. - 1/2 teaspoon) one to four times daily or as directed by a health professional. Place in mouth or purified water.

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Apis mel. 6x, Echinacea 6x, Apis mel. 15x, Arsenicum alb. 15x, Belladonna 15x, Bromium 15x, Bryonia 15x, Capsicum 15x, Chelidonium majus 15x, Cinchona 15x, Ferrum phos. 15x, Graphites 15x, Lycopodium 15x, Mancinella 15x, Merc. dulc. 15x, Mezereum 15x, Nux vom. 15x, Phos. 15x, Plantago 15x, Pulsatilla 15x, Rhus tox. 15x, Sepia 15x, Verbas cum 15x, Viola tric. 15x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as discomfort, itching, irritation, inflammation and swelling.

INACTIVE INGREDIENT SECTION

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

QUESTIONS SECTION

newtonlabs.net Questions? 1.800.448.7256
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

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

NEWTON homeopathics 
for **PETS**
Nurturing Naturally Since 1987™

NDC# 55714-4339-1

Ear Care

Formulated for symptoms associated with ear conditions such as discomfort, itching, irritation, inflammation, swelling and foul discharge.

1 fl oz (29.57 ml)

Directions: ORAL USE ONLY - SHAKE WELL.
Pets, under 50 lbs., give 3 drops orally (50 to 500 lbs. - 6 drops, over 500 lbs. - 1/2 teaspoon) one to four times daily or as directed by a healthcare professional. Place in mouth or purified water.


Active Ingredients: Apis mel. 15x, Arsenicum alb. 15x, Belladonna 15x, Bromium 15x, Bryonia 15x, Capsicum 15x, Chelidonium majus 15x, Cinchona 15x, Ferrum phosphoricum 15x, Graphites 15x, Lycopodium 15x, Mancinella 15x, Merc. dulc. 15x, Mezereum 15x, Nux vom. 15x, Phosphorus 15x, Plantago 15x, Pulsatilla 15x, Rhus toxicodendron 15x, Sepia 15x, Verbasicum 15x, Viola tric. 15x, Apis mel. 3x Echinacea 3x.

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

Stock# P022 Lot#

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

Warnings: 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 **PETS**

NDC# 55714-4283-1

Ear Care

Formulated for associated symptoms such as discomfort, itching, irritation, inflammation and swelling.

1 FL OZ (30 ML)

Directions: Pets, under 50 lbs., give 3 drops by mouth (50 to 500 lbs. - 6 drops, over 500 lbs. - 1/2 teaspoon) one to four times daily or as directed by a health professional. Place in mouth or purified water.

Active Ingredients: Equal parts of Apis mel. 6x, Echinacea 6x, Apis mel. 15x, Arsenicum alb. 15x, Belladonna 15x, Bromium 15x, Bryonia 15x, Capsicum 15x, Chelidonium maj. 15x, Cinchona 15x, Ferrum phos. 15x, Graphites 15x, Lycopodium 15x, Mancinella 15x, Merc. dulc. 15x, Mezereum 15x, Nux vom. 15x, Phos. 15x, Plantago 15x, Pulsatilla 15x, Rhus tox. 15x, Sepia 15x, Verbasicum 15x, Viola tric. 15x.

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

Stock# P022 Lot#

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.

EAR CARE

apis mel., arsenicum alb., belladonna, bromium, bryonia, capsicum, chelidonium majus, cinchona, ferrum phosphoricum, graphites, lycopodium, mancinella, merc. dulc., mezereum, nux vom., phosphorus, plantago, pulsatilla, rhus toxicodendron, sepia, verbasicum, viola tric., echinacea liquid

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:55714-4339
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
Bromine (UNII: SBV4XY874G) (Bromine - UNII:SBV4XY874G)	Bromine	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
Chelidonium Majus (UNII: 7E889U5RNN) (Chelidonium Majus - UNII:7E889U5RNN)	Chelidonium Majus	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
Ferrosoferric Phosphate (UNII: 91GQH8I5F7) (Ferrosoferric Phosphate - UNII:91GQH8I5F7)	Ferrosoferric Phosphate	15 [hp_X] in 1 mL
Graphite (UNII: 4QQN74LH4O) (Graphite - UNII:4QQN74LH4O)	Graphite	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
Hippomane Mancinella Fruiting Leafy Twig (UNII: HU6EYI2I1W) (Hippomane Mancinella Fruiting Leafy Twig - UNII:HU6EYI2I1W)	Hippomane Mancinella Fruiting Leafy Twig	15 [hp_X] in 1 mL
Calomel (UNII: J2D46N657D) (Calomel - UNII:J2D46N657D)	Calomel	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
Strychnos Nux-vomica Seed (UNII: 269XH13919) (Strychnos Nux-vomica Seed - UNII:269XH13919)	Strychnos Nux-vomica Seed	15 [hp_X] in 1 mL
Phosphorus (UNII: 27YLU75U4W) (Phosphorus - UNII:27YLU75U4W)	Phosphorus	15 [hp_X] in 1 mL
Plantago Major (UNII: W2469WNO6U) (Plantago Major - UNII:W2469WNO6U)	Plantago Major	15 [hp_X] in 1 mL
Pulsatilla Vulgaris (UNII: I76KB35JEV) (Pulsatilla Vulgaris - UNII:I76KB35JEV)	Pulsatilla Vulgaris	15 [hp_X] in 1 mL
Toxicodendron Pubescens Leaf (UNII: 6IO182RP7A) (Toxicodendron Pubescens Leaf - UNII:6IO182RP7A)	Toxicodendron Pubescens Leaf	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
Verbascum Thapsus (UNII: C9TD27U172) (Verbascum Thapsus - UNII:C9TD27U172)	Verbascum Thapsus	15 [hp_X] in 1 mL
Viola Tricolor (UNII: 9Q24RAI43V) (Viola Tricolor - UNII:9Q24RAI43V)	Viola Tricolor	15 [hp_X] in 1 mL
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	3 [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:55714-4339-1	29.57 mL in 1 BOTTLE, GLASS		
2	NDC:55714-4339-2	59.14 mL in 1 BOTTLE, GLASS		
3	NDC:55714-4339-0	14.78 mL in 1 BOTTLE, GLASS		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved homeopathic		07/15/2011	12/31/2018	

EAR CARE

apis mel., arsenicum alb., belladonna, bromium, bryonia, capsicum, chelidonium majus, cinchona, ferrum phosphoricum, graphites, lycopodium, mancinella, merc. dulc., mezereum, nux vom., phosphorus, plantago, pulsatilla, rhus toxicodendron, sepia, verbascum, viola tric., echinacea liquid

Product Information			
Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:55714-4283
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
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
Bromine (UNII: SBV4XY874G) (Bromine - UNII:SBV4XY874G)	Bromine	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
Chelidonium Majus (UNII: 7E889U5RNN) (Chelidonium Majus - UNII:7E889U5RNN)	Chelidonium Majus	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
Ferrosferric Phosphate (UNII: 91GQH8I5F7) (Ferrosferric Phosphate - UNII:91GQH8I5F7)	Ferrosferric Phosphate	15 [hp_X] in 1 mL
Graphite (UNII: 4QQN74LH4O) (Graphite - UNII:4QQN74LH4O)	Graphite	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

Hippomane Mancinella Fruiting Leafy Twig (UNII: HU6EYI2I1W) (Hippomane Mancinella Fruiting Leafy Twig - UNII:HU6EYI2I1W)	Hippomane Mancinella Fruiting Leafy Twig	15 [hp_X] in 1 mL
Calomel (UNII: J2D46N657D) (Calomel - UNII:J2D46N657D)	Calomel	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
Strychnos Nux-vomica Seed (UNII: 269XH13919) (Strychnos Nux-vomica Seed - UNII:269XH13919)	Strychnos Nux-vomica Seed	15 [hp_X] in 1 mL
Phosphorus (UNII: 27YLU75U4W) (Phosphorus - UNII:27YLU75U4W)	Phosphorus	15 [hp_X] in 1 mL
Plantago Major (UNII: W2469WNO6U) (Plantago Major - UNII:W2469WNO6U)	Plantago Major	15 [hp_X] in 1 mL
Pulsatilla Vulgaris (UNII: I76KB35JEV) (Pulsatilla Vulgaris - UNII:I76KB35JEV)	Pulsatilla Vulgaris	15 [hp_X] in 1 mL
Toxicodendron Pubescens Leaf (UNII: 6IO182RP7A) (Toxicodendron Pubescens Leaf - UNII:6IO182RP7A)	Toxicodendron Pubescens Leaf	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
Verbascum Thapsus (UNII: C9TD27U172) (Verbascum Thapsus - UNII:C9TD27U172)	Verbascum Thapsus	15 [hp_X] in 1 mL
Viola Tricolor (UNII: 9Q24RAI43V) (Viola Tricolor - UNII:9Q24RAI43V)	Viola Tricolor	15 [hp_X] in 1 mL
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	6 [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:55714-4283-1	30 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/14/2019	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture, api manufacture