

HAY FEVER - zerophyllum asphodeloides, alfalfa, avena sativa pollen, cynosurus cristatus pollen, echinochloa crus-galli pollen, poa pratensis pollen, anthoxanthum odoratum pollen, agrostis gigantea pollen, bromus secalinus pollen, alopecurus pratensis pollen, phleum pratense pollen, festuca pratensis pollen, holcus lanatus pollen, lolium perenne pollen, fagus sylvatica pollen, betula pendula pollen, quercus alba pollen, fraxinus excelsior pollen, corylus americana pollen, populus nigra pollen pellet
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.

Hay Fever

INDICATIONS & USAGE SECTION

Formulated for associated symptoms of late Summer and Fall pollens such nasal catarrh, post~nasal drip, sneezing, glandular swellings and pharyngitis.

DOSAGE & ADMINISTRATION SECTION

Directions: Ages 12 and up, take 6 pellets by mouth (ages 0 to 11, give 3 pellets) as needed or as directed by a health professional. Under age 2, crush/dissolve pellets in purified water.

OTC - ACTIVE INGREDIENT SECTION

Xerophyllum 30x, Alfalfa 15x, Allersodes 15x, Allium cepa 15x, Ambrosia 15x, Ammon. carb. 15x, Aralia rac. 15x, Arsenicum alb. 15x, Artemisia 15x, Bellis 15x, Berber. vulg. 15x, Bryonia 15x, Chelidonium maj. 15x, Eupatorium perf. 15x, Euphrasia 15x, Gelsemium 15x, Hepar sulph. calc. 15x, Histaminum hydrochloricum 15x, Kali bic. 15x, Kali iod. 15x, Lachesis 15x, Lycopodium 15x, Nat.mur. 15x, Sabadilla 15x, Solidago 15x, Trillium 15x, Ustilago maidis 15x, Apis mel. 3x, Echinacea 3x, Hydrastis 3x, Taraxacum 3x.

OTC - PURPOSE SECTION

Formulated for associated symptoms of late Summer and Fall pollens such as nasal catarrh, post~nasal drip, sneezing, glandular swellings and pharyngitis.

INACTIVE INGREDIENT SECTION

Inactive Ingredients: Gluten-free, non-GMO, beet-derived sucrose pellets.

QUESTIONS SECTION

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

WARNINGS SECTION

Warning: 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

HAY FEVER

zerophyllum asphodeloides, alfalfa, avena sativa pollen, cynosurus cristatus pollen, echinocloa crus-galli pollen, poa pratensis pollen, anthoxanthum odoratum pollen, agrostis gigantea pollen, bromus secalinus pollen, alopecurus pratensis pollen, phleum pratense pollen, festuca pratensis pollen, holcus lanatus pollen, lolium perenne pollen, fagus sylvatica pollen, betula pendula pollen, quercus alba pollen, fraxinus excelsior pollen, corylus americana pollen, populus nigra pollen pellet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:55714-4433
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Xerophyllum Asphodeloides (UNII: 9I4XB1GP2B) (Xerophyllum Asphodeloides - UNII:9I4XB1GP2B)	Xerophyllum Asphodeloides	30 [hp_X] in 1 g

Alfalfa (UNII: DJO934BRBD) (Alfalfa - UNII:DJO934BRBD)	Alfalfa	15 [hp_X] in 1 g
Avena Sativa Pollen (UNII: A7IKY24TR7) (Avena Sativa Pollen - UNII:A7IKY24TR7)	Avena Sativa Pollen	15 [hp_X] in 1 g
Cynosurus Cristatus Pollen (UNII: SES68PF95U) (Cynosurus Cristatus Pollen - UNII:SES68PF95U)	Cynosurus Cristatus Pollen	15 [hp_X] in 1 g
Echinochloa Crus-galli Pollen (UNII: 6941ZR795V) (Echinochloa Crus-galli Pollen - UNII:6941ZR795V)	Echinochloa Crus-galli Pollen	15 [hp_X] in 1 g
Poa Pratensis Pollen (UNII: SCB8J7LS3T) (Poa Pratensis Pollen - UNII:SCB8J7LS3T)	Poa Pratensis Pollen	15 [hp_X] in 1 g
Anthoxanthum Odoratum Pollen (UNII: 2KIK19R45Y) (Anthoxanthum Odoratum Pollen - UNII:2KIK19R45Y)	Anthoxanthum Odoratum Pollen	15 [hp_X] in 1 g
Agrostis Gigantea Pollen (UNII: HU8V6E7HOA) (Agrostis Gigantea Pollen - UNII:HU8V6E7HOA)	Agrostis Gigantea Pollen	15 [hp_X] in 1 g
Bromus Secalinus Pollen (UNII: Q4T1SJ3046) (Bromus Secalinus Pollen - UNII:Q4T1SJ3046)	Bromus Secalinus Pollen	15 [hp_X] in 1 g
Alopecurus Pratensis Pollen (UNII: DG1ZL6W96V) (Alopecurus Pratensis Pollen - UNII:DG1ZL6W96V)	Alopecurus Pratensis Pollen	15 [hp_X] in 1 g
Phleum Pratense Pollen (UNII: 65M88RW2EG) (Phleum Pratense Pollen - UNII:65M88RW2EG)	Phleum Pratense Pollen	15 [hp_X] in 1 g
Festuca Pratensis Pollen (UNII: A0WFQ8P6N1) (Festuca Pratensis Pollen - UNII:A0WFQ8P6N1)	Festuca Pratensis Pollen	15 [hp_X] in 1 g
Holcus Lanatus Pollen (UNII: 70O1TP6H01) (Holcus Lanatus Pollen - UNII:70O1TP6H01)	Holcus Lanatus Pollen	15 [hp_X] in 1 g
Lolium Perenne Pollen (UNII: 4T81LB52R0) (Lolium Perenne Pollen - UNII:4T81LB52R0)	Lolium Perenne Pollen	15 [hp_X] in 1 g
Fagus Sylvatica Pollen (UNII: 63218N1ZBI) (Fagus Sylvatica Pollen - UNII:63218N1ZBI)	Fagus Sylvatica Pollen	15 [hp_X] in 1 g
Betula Pendula Pollen (UNII: ZL5TV40C5Y) (Betula Pendula Pollen - UNII:ZL5TV40C5Y)	Betula Pendula Pollen	15 [hp_X] in 1 g
Quercus Alba Pollen (UNII: Z4Y9ZSV4KK) (Quercus Alba Pollen - UNII:Z4Y9ZSV4KK)	Quercus Alba Pollen	15 [hp_X] in 1 g
Fraxinus Excelsior Pollen (UNII: 1824QUA0U3) (Fraxinus Excelsior Pollen - UNII:1824QUA0U3)	Fraxinus Excelsior Pollen	15 [hp_X] in 1 g
Corylus Americana Pollen (UNII: ZGS382Y3AV) (Corylus Americana Pollen - UNII:ZGS382Y3AV)	Corylus Americana Pollen	15 [hp_X] in 1 g
Populus Nigra Pollen (UNII: 0MGE63QPFJ) (Populus Nigra Pollen - UNII:0MGE63QPFJ)	Populus Nigra Pollen	15 [hp_X] in 1 g
Platanus Orientalis Pollen (UNII: Y1A4835L6K) (Platanus Orientalis Pollen - UNII:Y1A4835L6K)	Platanus Orientalis Pollen	15 [hp_X] in 1 g
Ulmus Glabra Pollen (UNII: T2K08L297Q) (Ulmus Glabra Pollen - UNII:T2K08L297Q)	Ulmus Glabra Pollen	15 [hp_X] in 1 g
Salix Alba Pollen (UNII: WQ580684IZ) (Salix Alba Pollen - UNII:WQ580684IZ)	Salix Alba Pollen	15 [hp_X] in 1 g
Narcissus Pseudonarcissus (UNII: Q2D0SKW2P4) (Narcissus Pseudonarcissus - UNII:Q2D0SKW2P4)	Narcissus Pseudonarcissus	15 [hp_X] in 1 g
Rosa Canina Flower (UNII: 81MCR2UQ6Q) (Rosa Canina Flower - UNII:81MCR2UQ6Q)	Rosa Canina Flower	15 [hp_X] in 1 g
Lilium Candidum Flower (UNII: COV655U2CJ) (Lilium Candidum Flower - UNII:COV655U2CJ)	Lilium Candidum Flower	15 [hp_X] in 1 g
Primula Vulgaris (UNII: KZ3PRK2V0J) (Primula Vulgaris - UNII:KZ3PRK2V0J)	Primula Vulgaris	15 [hp_X] in 1 g
Dianthus Caryophyllus Flower (UNII: B0D836E90S) (Dianthus Caryophyllus Flower - UNII:B0D836E90S)	Dianthus Caryophyllus Flower	15 [hp_X] in 1 g
Ulex Europaeus Flower (UNII: 398DBS1PXN) (Ulex Europaeus Flower - UNII:398DBS1PXN)	Ulex Europaeus Flower	15 [hp_X] in 1 g
Cytisus Scoparius Pollen (UNII: I0NS0040GH) (Cytisus Scoparius Pollen - UNII:I0NS0040GH)	Cytisus Scoparius Pollen	15 [hp_X] in 1 g
Calluna Vulgaris Pollen (UNII: 5Q1IE9V5YZ) (Calluna Vulgaris Pollen - UNII:5Q1IE9V5YZ)	Calluna Vulgaris Pollen	15 [hp_X] in 1 g

Crataegus Monogyna Pollen (UNII: X6049S3TX1) (Crataegus Monogyna Pollen - UNII:X6049S3TX1)	Crataegus Monogyna Pollen	15 [hp_X] in 1 g
Aconitum Napellus (UNII: U0NQ8555JD) (Aconitum Napellus - UNII:U0NQ8555JD)	Aconitum Napellus	15 [hp_X] in 1 g
Arundo Pliniana Root (UNII: ZXE7LB03WC) (Arundo Pliniana Root - UNII:ZXE7LB03WC)	Arundo Pliniana Root	15 [hp_X] in 1 g
Dysphania Ambrosioides (UNII: 4H5RSU087I) (Dysphania Ambrosioides - UNII:4H5RSU087I)	Dysphania Ambrosioides	15 [hp_X] in 1 g
Helianthemum Canadense (UNII: 46G3W789Q3) (Helianthemum Canadense - UNII:46G3W789Q3)	Helianthemum Canadense	15 [hp_X] in 1 g
Drosera Rotundifolia (UNII: QR44N9XPJQ) (Drosera Rotundifolia - UNII:QR44N9XPJQ)	Drosera Rotundifolia	15 [hp_X] in 1 g
Solanum Dulcamara Top (UNII: KPS1B1162N) (Solanum Dulcamara Top - UNII:KPS1B1162N)	Solanum Dulcamara Top	15 [hp_X] in 1 g
Ledum Palustre Twig (UNII: 877L01IZ0P) (Ledum Palustre Twig - UNII:877L01IZ0P)	Ledum Palustre Twig	15 [hp_X] in 1 g
Onosmodium Virginianum Whole (UNII: 604NK4250S) (Onosmodium Virginianum Whole - UNII:604NK4250S)	Onosmodium Virginianum Whole	15 [hp_X] in 1 g
Populus Tremuloides Leaf (UNII: 7IIF57D9E0) (Populus Tremuloides Leaf - UNII:7IIF57D9E0)	Populus Tremuloides Leaf	15 [hp_X] in 1 g
Populus Tremuloides Bark (UNII: 5543O0CEID) (Populus Tremuloides Bark - UNII:5543O0CEID)	Populus Tremuloides Bark	15 [hp_X] in 1 g
Pulsatilla Vulgaris (UNII: I76KB35JEV) (Pulsatilla Vulgaris - UNII:I76KB35JEV)	Pulsatilla Vulgaris	15 [hp_X] in 1 g
Sanguinaria Canadensis Root (UNII: N9288CD508) (Sanguinaria Canadensis Root - UNII:N9288CD508)	Sanguinaria Canadensis Root	15 [hp_X] in 1 g
Datura Stramonium (UNII: G6W4F0V8Z3) (Datura Stramonium - UNII:G6W4F0V8Z3)	Datura Stramonium	15 [hp_X] in 1 g
Elymus Repens Root (UNII: 3IXW0F6P8W) (Elymus Repens Root - UNII:3IXW0F6P8W)	Elymus Repens Root	15 [hp_X] in 1 g
Urtica Urens (UNII: IHN2NQ50F9) (Urtica Urens - UNII:IHN2NQ50F9)	Urtica Urens	15 [hp_X] in 1 g
Wyethia Helenioides Root (UNII: J10PD1AQ0N) (Wyethia Helenioides Root - UNII:J10PD1AQ0N)	Wyethia Helenioides Root	15 [hp_X] in 1 g
Onion (UNII: 492225Q21H) (Onion - UNII:492225Q21H)	Onion	15 [hp_X] in 1 g
Ambrosia Artemisiifolia (UNII: 9W34L2CQ9A) (Ambrosia Artemisiifolia - UNII:9W34L2CQ9A)	Ambrosia Artemisiifolia	15 [hp_X] in 1 g
Ammonium Carbonate (UNII: NJ5VT0FKLJ) (Carbonate Ion - UNII:7UJQ5OPE7D)	Carbonate Ion	15 [hp_X] in 1 g
Aralia Racemosa Root (UNII: T90W4582DU) (Aralia Racemosa Root - UNII:T90W4582DU)	Aralia Racemosa Root	15 [hp_X] in 1 g
Arsenic Trioxide (UNII: S7V92P67HO) (Arsenic Cation (3+) - UNII:C96613F5AV)	Arsenic Cation (3+)	15 [hp_X] in 1 g
Artemisia Vulgaris Root (UNII: 32MP823R8S) (Artemisia Vulgaris Root - UNII:32MP823R8S)	Artemisia Vulgaris Root	15 [hp_X] in 1 g
Bellis Perennis (UNII: 2HU33I03UY) (Bellis Perennis - UNII:2HU33I03UY)	Bellis Perennis	15 [hp_X] in 1 g
Berberis Vulgaris Root Bark (UNII: 1TH8Q20J0U) (Berberis Vulgaris Root Bark - UNII:1TH8Q20J0U)	Berberis Vulgaris Root Bark	15 [hp_X] in 1 g
Bryonia Alba Root (UNII: T7J046YI2B) (Bryonia Alba Root - UNII:T7J046YI2B)	Bryonia Alba Root	15 [hp_X] in 1 g
Chelidonium Majus (UNII: 7E889U5RNN) (Chelidonium Majus - UNII:7E889U5RNN)	Chelidonium Majus	15 [hp_X] in 1 g
Eupatorium Perfoliatum Flowering Top (UNII: 1W0775VX6E) (Eupatorium Perfoliatum Flowering Top - UNII:1W0775VX6E)	Eupatorium Perfoliatum Flowering Top	15 [hp_X] in 1 g
Euphrasia Stricta (UNII: C9642I91WL) (Euphrasia Stricta - UNII:C9642I91WL)	Euphrasia Stricta	15 [hp_X] in 1 g
Gelsemium Sempervirens Root (UNII: 639KR60Q1Q) (Gelsemium Sempervirens Root - UNII:639KR60Q1Q)	Gelsemium Sempervirens Root	15 [hp_X] in 1 g

Calcium Sulfide (UNII: 1MBW07J51Q) (Calcium Sulfide - UNII:1MBW07J51Q)	Calcium Sulfide	15 [hp_X] in 1 g
Histamine Dihydrochloride (UNII: 3POA0Q644U) (Histamine - UNII:820484N8I3)	Histamine Dihydrochloride	15 [hp_X] in 1 g
Potassium Dichromate (UNII: T4423S18FM) (Dichromate Ion - UNII:9LKY4BFN2V)	Potassium Dichromate	15 [hp_X] in 1 g
Potassium Iodide (UNII: 1C4QK22F9J) (Iodide Ion - UNII:09G4I6V86Q)	Iodide Ion	15 [hp_X] in 1 g
Lachesis Muta Venom (UNII: VSW71SS07I) (Lachesis Muta Venom - UNII:VSW71SS07I)	Lachesis Muta Venom	15 [hp_X] in 1 g
Lycopodium Clavatum Spore (UNII: C88X29Y479) (Lycopodium Clavatum Spore - UNII:C88X29Y479)	Lycopodium Clavatum Spore	15 [hp_X] in 1 g
Sodium Chloride (UNII: 451W47IQ8X) (Chloride Ion - UNII:Q32ZN48698)	Sodium Chloride	15 [hp_X] in 1 g
Schoenocaulon Officinale Seed (UNII: 6NAF1689IO) (Schoenocaulon Officinale Seed - UNII:6NAF1689IO)	Schoenocaulon Officinale Seed	15 [hp_X] in 1 g
Solidago Virgaurea Flowering Top (UNII: 5405K23S50) (Solidago Virgaurea Flowering Top - UNII:5405K23S50)	Solidago Virgaurea Flowering Top	15 [hp_X] in 1 g
Trillium Erectum Root (UNII: AHW6F0T2X0) (Trillium Erectum Root - UNII:AHW6F0T2X0)	Trillium Erectum Root	15 [hp_X] in 1 g
Ustilago Maydis (UNII: 4K7Z7K7SWG) (Ustilago Maydis - UNII:4K7Z7K7SWG)	Ustilago Maydis	15 [hp_X] in 1 g
Apis Mellifera (UNII: 7S82P3R43Z) (Apis Mellifera - UNII:7S82P3R43Z)	Apis Mellifera	3 [hp_X] in 1 g
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	3 [hp_X] in 1 g
Goldenseal (UNII: ZW3Z11D0JV) (Goldenseal - UNII:ZW3Z11D0JV)	Goldenseal	3 [hp_X] in 1 g
Taraxacum Officinale (UNII: 39981FM375) (Taraxacum Officinale - UNII:39981FM375)	Taraxacum Officinale	3 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
Sucrose (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-4433-1	28 g in 1 BOTTLE, GLASS		
2	NDC:55714-4433-2	57 g in 1 BOTTLE, GLASS		
3	NDC:55714-4433-0	7 g in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		06/01/2011	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-4433)

Revised: 6/2011

Newton Laboratories, Inc.