

**FOOD ALLERGY - ADDITIVE - e102 tartrazine, e104 quinoline yellow, e110 sunset/orange yellow, e122 carmoisine, e123 armaranth, e124 cochineal red a, e127 erythrosine, d128 red 2g, e132 indigotine, e141 copper/chlorophyll complex, e142 green s, e211 sodium benzoate, e212 potassium benzoate, e216 propyl p-hydroxybenzoate, e223 sodium metabisulphate, e231 orthophenylphenol, e250 sodium nitrate, e300 ascorbic acid, e399 sodium mono/bi/triphosphate, e951 aspartame, monosodium glutamate, beef, pork, lamb, chicken, turkey, clam 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.*

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**Food Allergy - Additive**

**INDICATIONS & USAGE SECTION**

Formulated for associated symptoms such as itching, swelling, headaches, labored breathing and digestive upset.

**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. Sensitive persons begin with 1 pellet and gradually increase to full dose.

**OTC - ACTIVE INGREDIENT SECTION**

Allersodes 60x, Allersodes 15x, Histaminum hydrochloricum 15x, Lycopersicum 15x, Saccharinum 15x, Sac. lac. 15x, Solanum tub. 15x, Torula cerevisiae 15x, Ustilago maidis 15x, Aconitum nap. 10x, Antimon.crud. 10x, Arsenicum alb. 10x, Baptisia 10x, Cinchona 10x, Gelsemium 10x, Ipecac. 10x, Lachesis 10x, Ledum 10x, Lycopodium 10x, Nat. mur. 10x, Phos. 10x, Podoph. pelt. 10x, Pulsatilla 10x, Rhus tox. 10x, Sepia 10x, Sulphur 10x, Urtica ur. 10x, Iris vers. 3x, Solidago 3x.

**OTC - PURPOSE SECTION**

Formulated for associated symptoms such as itching, swelling, headaches, labored breathing and digestive upset.

**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

## FOOD ALLERGY - ADDITIVE

e102 tartrazine, e104 quinoline yellow, e110 sunset/orange yellow, e122 carmoisine, e123 armaranth, e124 cochineal red a, e127 erythrosine, d128 red 2g, e 132 indigotine, e141 copper/chlorophyll complex, e142 green s, e211 sodium benzoate, e212 potassium benzoate, e216 propyl p-hydroxybenzoate, e223 sodium metabisulphate, e231 orthophenylphenol, e250 sodium nitrate, e300 ascorbic acid, e399 sodium mono/bi/triphosphate, e951 aspartame, monosodium glutamate, beef, pork, lamb, chicken, turkey, clam pellet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2315
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Egg (UNII: 29 1P45F896) (Egg - UNII:29 1P45F896)	Egg	60 [hp_X] in 1 g

<b>Fd&amp;c Yellow No. 5</b> (UNII: I753WB2F1M) (Fd&c Yellow No. 5 - UNII:I753WB2F1M)	Fd&c Yellow No. 5	60 [hp_X] in 1 g
<b>D&amp;c Yellow No. 10</b> (UNII: 35SW5USQ3G) (D&c Yellow No. 10 - UNII:35SW5USQ3G)	D&c Yellow No. 10	60 [hp_X] in 1 g
<b>Fd&amp;c Yellow No. 6</b> (UNII: H77VEI93A8) (Food Yellow 3 Free Acid - UNII:G2B7JWK1GG)	Fd&c Yellow No. 6	60 [hp_X] in 1 g
<b>Carmoisine</b> (UNII: DR4641L47F) (Carmoisine - UNII:DR4641L47F)	Carmoisine	60 [hp_X] in 1 g
<b>Amaranth</b> (UNII: 37RBV3X49K) (Amaranth Acid - UNII:02J7X17ZUQ)	Amaranth	60 [hp_X] in 1 g
<b>Ponceau 4r</b> (UNII: Z525CBK9PG) (Ponceau 4r - UNII:Z525CBK9PG)	Ponceau 4r	60 [hp_X] in 1 g
<b>Fd&amp;c Red No. 3</b> (UNII: PN2ZH5LOQY) (Tetraiodofluorescein - UNII:1A878FZQ9B)	Fd&c Red No. 3	60 [hp_X] in 1 g
<b>Acid Red 1</b> (UNII: 3365R6427R) (Acid Red 1 - UNII:3365R6427R)	Acid Red 1	60 [hp_X] in 1 g
<b>Fd&amp;c Blue No. 2</b> (UNII: L06K8R7DQK) (Fd&c Blue No. 2 - UNII:L06K8R7DQK)	Fd&c Blue No. 2	60 [hp_X] in 1 g
<b>Sodium Copper Chlorophyllin</b> (UNII: 1D276TYV9O) (Sodium - UNII:9NEZ333N27)	Sodium Copper Chlorophyllin	60 [hp_X] in 1 g
<b>Acid Green 50</b> (UNII: 9B7E8Y9D0X) (Acid Green 50 - UNII:9B7E8Y9D0X)	Acid Green 50	60 [hp_X] in 1 g
<b>Sodium Benzoate</b> (UNII: OJ245FE5EU) (Benzoic Acid - UNII:8SKN0B0MIM)	Sodium Benzoate	60 [hp_X] in 1 g
<b>Potassium Benzoate</b> (UNII: 763YQN2K7K) (Potassium - UNII:RWP5GA015D)	Potassium Benzoate	60 [hp_X] in 1 g
<b>Propylparaben</b> (UNII: Z8IX2SC1OH) (Propylparaben - UNII:Z8IX2SC1OH)	Propylparaben	60 [hp_X] in 1 g
<b>Sodium Dithionate</b> (UNII: RPF7Z41GAW) (Sodium - UNII:9NEZ333N27)	Sodium Dithionate	60 [hp_X] in 1 g
<b>2-phenylphenol</b> (UNII: D343Z75HT8) (2-phenylphenol - UNII:D343Z75HT8)	2-phenylphenol	60 [hp_X] in 1 g
<b>Sodium Nitrite</b> (UNII: M0KG633D4F) (Nitrite Ion - UNII:J39976L608)	Sodium Nitrite	60 [hp_X] in 1 g
<b>Ascorbic Acid</b> (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 [hp_X] in 1 g
<b>Sodium Tripolyphosphate</b> (UNII: 5HK03SA80J) (Tripolyphosphate Ion - UNII:5798IYA5AY)	Sodium Tripolyphosphate	60 [hp_X] in 1 g
<b>Aspartame</b> (UNII: Z0H242BBR1) (Aspartame - UNII:Z0H242BBR1)	Aspartame	60 [hp_X] in 1 g
<b>Monosodium Glutamate</b> (UNII: W81N5U6R6U) (Glutamic Acid - UNII:3KX376GY7L)	Monosodium Glutamate	60 [hp_X] in 1 g
<b>Beef</b> (UNII: 4PIB2155QP) (Beef - UNII:4PIB2155QP)	Beef	60 [hp_X] in 1 g
<b>Pork</b> (UNII: O138UB266J) (Pork - UNII:O138UB266J)	Pork	60 [hp_X] in 1 g
<b>Lamb</b> (UNII: FOF26T73HA) (Lamb - UNII:FOF26T73HA)	Lamb	60 [hp_X] in 1 g
<b>Chicken</b> (UNII: 0X8Q245Y7B) (Chicken - UNII:0X8Q245Y7B)	Chicken	60 [hp_X] in 1 g
<b>Turkey</b> (UNII: 8E9NT44R8I) (Turkey - UNII:8E9NT44R8I)	Turkey	60 [hp_X] in 1 g
<b>Quahog, Unspecified</b> (UNII: 226LY0AFR9) (Quahog, Unspecified - UNII:226LY0AFR9)	Quahog, Unspecified	60 [hp_X] in 1 g
<b>Crab Leg, Unspecified</b> (UNII: S1VF61QLO9) (Crab Leg, Unspecified - UNII:S1VF61QLO9)	Crab Leg, Unspecified	60 [hp_X] in 1 g
<b>Oyster, Unspecified</b> (UNII: S614XWR17V) (Oyster, Unspecified - UNII:S614XWR17V)	Oyster, Unspecified	60 [hp_X] in 1 g
<b>Shrimp, Unspecified</b> (UNII: 1891LE191T) (Shrimp, Unspecified - UNII:1891LE191T)	Shrimp, Unspecified	60 [hp_X] in 1 g

<b>Scallop, Unspecified</b> (UNII: D380C73WOU) (Scallop, Unspecified - UNII:D380C73WOU)	Scallop, Unspecified	60 [hp_X] in 1 g
<b>Amanita Muscaria Fruiting Body</b> (UNII: DIF093I037) (Amanita Muscaria Fruiting Body - UNII:DIF093I037)	Amanita Muscaria Fruiting Body	15 [hp_X] in 1 g
<b>Onion</b> (UNII: 492225Q21H) (Onion - UNII:492225Q21H)	Onion	15 [hp_X] in 1 g
<b>Garlic</b> (UNII: V1V998DC17) (Garlic - UNII:V1V998DC17)	Garlic	15 [hp_X] in 1 g
<b>Anacardium Occidentale Fruit</b> (UNII: 4A10JR4E7E) (Anacardium Occidentale Fruit - UNII:4A10JR4E7E)	Anacardium Occidentale Fruit	15 [hp_X] in 1 g
<b>Lycoperdon Utriforme Fruiting Body</b> (UNII: K2A74U428F) (Lycoperdon Utriforme Fruiting Body - UNII:K2A74U428F)	Lycoperdon Utriforme Fruiting Body	15 [hp_X] in 1 g
<b>Caffeine</b> (UNII: 3G6A5W338E) (Caffeine - UNII:3G6A5W338E)	Caffeine	15 [hp_X] in 1 g
<b>Capsicum</b> (UNII: 00UK7646FG) (Capsicum - UNII:00UK7646FG)	Capsicum	15 [hp_X] in 1 g
<b>Cinnamon</b> (UNII: 5S29HWU6QB) (Cinnamon - UNII:5S29HWU6QB)	Cinnamon	15 [hp_X] in 1 g
<b>Cynara Scolymus Leaf</b> (UNII: B71UA545DE) (Cynara Scolymus Leaf - UNII:B71UA545DE)	Cynara Scolymus Leaf	15 [hp_X] in 1 g
<b>Alpine Strawberry</b> (UNII: CG6IX3GCMU) (Alpine Strawberry - UNII:CG6IX3GCMU)	Alpine Strawberry	15 [hp_X] in 1 g
<b>Abrus Precatorius Seed</b> (UNII: 3OM8I6L7CD) (Abrus Precatorius Seed - UNII:3OM8I6L7CD)	Abrus Precatorius Seed	15 [hp_X] in 1 g
<b>Glycyrrhiza Glabra</b> (UNII: 2788Z9758H) (Glycyrrhiza Glabra - UNII:2788Z9758H)	Glycyrrhiza Glabra	15 [hp_X] in 1 g
<b>Mentha Piperita</b> (UNII: 79M2M2UDA9) (Mentha Piperita - UNII:79M2M2UDA9)	Mentha Piperita	15 [hp_X] in 1 g
<b>Nutmeg</b> (UNII: AEE24M3MQ9) (Nutmeg - UNII:AEE24M3MQ9)	Nutmeg	15 [hp_X] in 1 g
<b>Lactose</b> (UNII: J2B2A4N98G) (Anhydrous Lactose - UNII:3SY5LH9PMK)	Lactose	15 [hp_X] in 1 g
<b>Black Mustard Seed</b> (UNII: 8LTY55LQ8D) (Black Mustard Seed - UNII:8LTY55LQ8D)	Black Mustard Seed	15 [hp_X] in 1 g
<b>Solanum Nigrum Whole</b> (UNII: 0FMD6WV47M) (Solanum Nigrum Whole - UNII:0FMD6WV47M)	Solanum Nigrum Whole	15 [hp_X] in 1 g
<b>Allylthiourea</b> (UNII: 706IDJ14B7) (Allylthiourea - UNII:706IDJ14B7)	Allylthiourea	15 [hp_X] in 1 g
<b>Ustilago Maydis</b> (UNII: 4K7Z7K7SWG) (Ustilago Maydis - UNII:4K7Z7K7SWG)	Ustilago Maydis	15 [hp_X] in 1 g
<b>Ginger</b> (UNII: C5529G5JPQ) (Ginger - UNII:C5529G5JPQ)	Ginger	15 [hp_X] in 1 g
<b>Brazil Nut</b> (UNII: XKR79OET1K) (Brazil Nut - UNII:XKR79OET1K)	Brazil Nut	15 [hp_X] in 1 g
<b>Hazelnut, Unspecified</b> (UNII: IW0OM96F6O) (Hazelnut, Unspecified - UNII:IW0OM96F6O)	Hazelnut, Unspecified	15 [hp_X] in 1 g
<b>Peanut</b> (UNII: QE1QX6B99R) (Peanut - UNII:QE1QX6B99R)	Peanut	15 [hp_X] in 1 g
<b>Trout, Unspecified</b> (UNII: 7TI7U5PF2U) (Trout, Unspecified - UNII:7TI7U5PF2U)	Trout, Unspecified	15 [hp_X] in 1 g
<b>Cod, Unspecified</b> (UNII: 8D6Q5LNG3D) (Cod, Unspecified - UNII:8D6Q5LNG3D)	Cod, Unspecified	15 [hp_X] in 1 g
<b>Tuna, Unspecified</b> (UNII: V2T3IHT3E2) (Tuna, Unspecified - UNII:V2T3IHT3E2)	Tuna, Unspecified	15 [hp_X] in 1 g
<b>Salmon, Unspecified</b> (UNII: 6122W2M0GB) (Salmon, Unspecified - UNII:6122W2M0GB)	Salmon, Unspecified	15 [hp_X] in 1 g
<b>Herring, Unspecified</b> (UNII: 34EX28T4C1) (Herring, Unspecified - UNII:34EX28T4C1)	Herring, Unspecified	15 [hp_X] in 1 g
<b>Histamine Dihydrochloride</b> (UNII: 3POA0Q644U) (Histamine - UNII:820484N8I3)	Histamine Dihydrochloride	15 [hp_X] in 1 g

<b>Solanum Lycopersicum</b> (UNII: 0243Q4990L) (Solanum Lycopersicum - UNII:0243Q4990L)	Solanum Lycopersicum	15 [hp_X] in 1 g
<b>Saccharin</b> (UNII: FST467XS7D) (Saccharin - UNII:FST467XS7D)	Saccharin	15 [hp_X] in 1 g
<b>Solanum Tuberosum</b> (UNII: 2A8I57T4MX) (Solanum Tuberosum - UNII:2A8I57T4MX)	Solanum Tuberosum	15 [hp_X] in 1 g
<b>Saccharomyces Cerevisiae</b> (UNII: 978D8U419H) (Saccharomyces Cerevisiae - UNII:978D8U419H)	Saccharomyces Cerevisiae	15 [hp_X] in 1 g
<b>Aconitum Napellus</b> (UNII: U0NQ8555JD) (Aconitum Napellus - UNII:U0NQ8555JD)	Aconitum Napellus	10 [hp_X] in 1 g
<b>Antimony Trisulfide</b> (UNII: F79059A38U) (Antimony Cation (3+) - UNII:069647RPT5)	Antimony Trisulfide	10 [hp_X] in 1 g
<b>Arsenic Trioxide</b> (UNII: S7V92P67HO) (Arsenic Cation (3+) - UNII:C96613F5AV)	Arsenic Trioxide	10 [hp_X] in 1 g
<b>Baptisia Tinctoria Root</b> (UNII: 5EF0HWI5WU) (Baptisia Tinctoria Root - UNII:5EF0HWI5WU)	Baptisia Tinctoria Root	10 [hp_X] in 1 g
<b>Cinchona Officinalis Bark</b> (UNII: S003A158SB) (Cinchona Officinalis Bark - UNII:S003A158SB)	Cinchona Officinalis Bark	10 [hp_X] in 1 g
<b>Gelsemium Sempervirens Root</b> (UNII: 639KR60Q1Q) (Gelsemium Sempervirens Root - UNII:639KR60Q1Q)	Gelsemium Sempervirens Root	10 [hp_X] in 1 g
<b>Ipecac</b> (UNII: 62IBC8233L) (Ipecac - UNII:62IBC8233L)	Ipecac	10 [hp_X] in 1 g
<b>Lachesis Muta Venom</b> (UNII: VSW71SS07I) (Lachesis Muta Venom - UNII:VSW71SS07I)	Lachesis Muta Venom	10 [hp_X] in 1 g
<b>Ledum Palustre Twig</b> (UNII: 877L01IZ0P) (Ledum Palustre Twig - UNII:877L01IZ0P)	Ledum Palustre Twig	10 [hp_X] in 1 g
<b>Lycopodium Clavatum Spore</b> (UNII: C88X29Y479) (Lycopodium Clavatum Spore - UNII:C88X29Y479)	Lycopodium Clavatum Spore	10 [hp_X] in 1 g
<b>Sodium Chloride</b> (UNII: 451W47IQ8X) (Chloride Ion - UNII:Q32ZN48698)	Sodium Chloride	10 [hp_X] in 1 g
<b>Phosphorus</b> (UNII: 27YLU75U4W) (Phosphorus - UNII:27YLU75U4W)	Phosphorus	10 [hp_X] in 1 g
<b>Podophyllum</b> (UNII: 2S713A4VP3) (Podophyllum - UNII:2S713A4VP3)	Podophyllum	10 [hp_X] in 1 g
<b>Pulsatilla Vulgaris</b> (UNII: I76KB35JEV) (Pulsatilla Vulgaris - UNII:I76KB35JEV)	Pulsatilla Vulgaris	10 [hp_X] in 1 g
<b>Toxicodendron Pubescens Leaf</b> (UNII: 6IO182RP7A) (Toxicodendron Pubescens Leaf - UNII:6IO182RP7A)	Toxicodendron Pubescens Leaf	10 [hp_X] in 1 g
<b>Sepia Officinalis Juice</b> (UNII: QDL83WN8C2) (Sepia Officinalis Juice - UNII:QDL83WN8C2)	Sepia Officinalis Juice	10 [hp_X] in 1 g
<b>Sulfur</b> (UNII: 70FD1KFU70) (Sulfur - UNII:70FD1KFU70)	Sulfur	10 [hp_X] in 1 g
<b>Urtica Urens</b> (UNII: IHN2NQ5OF9) (Urtica Urens - UNII:IHN2NQ5OF9)	Urtica Urens	10 [hp_X] in 1 g
<b>Iris Versicolor Root</b> (UNII: X43D4L3DQC) (Iris Versicolor Root - UNII:X43D4L3DQC)	Iris Versicolor Root	3 [hp_X] in 1 g
<b>Solidago Virgaurea Flowering Top</b> (UNII: 5405K23S50) (Solidago Virgaurea Flowering Top - UNII:5405K23S50)	Solidago Virgaurea Flowering Top	3 [hp_X] in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Sucrose</b> (UNII: C151H8M554)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:55714-2315-1	28 g in 1 BOTTLE, GLASS		
2	NDC:55714-2315-2	57 g in 1 BOTTLE, GLASS		
3	NDC:55714-2315-0	7 g 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(55714-2315)

Revised: 3/2011

Newton Laboratories, Inc.