

FOOD ADDITIVES- iris versicolor, solidago virgaurea, aconitum napellus, agaricus muscarius, allium cepa, allium sativum, antimonium crudum, arsenicum album, baptisia tinctoria, bovista, caffeinum, capsicum annuum, cinchona officinalis, cinnamomum, coccus cacti, cynara scolymus, fragaria vesca, gelsemium sempervirens, histaminum hydrochloricum, ipecacuanha, jequerity, juglans regia, lachesis mutus, ledum palustre, lycopodium clavatum, mentha piperita, natrum muriaticum, nux moschata, 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.

Food 2544L

INDICATIONS & USAGE SECTION

Formulated for associated symptoms such as itching, swelling, headaches, indigestion, vomiting and cramping.

DOSAGE & ADMINISTRATION SECTION

Directions: Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) as needed or directed by a health professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Iris versicolor 6x, Solidago virgaurea 6x, Aconitum napellus 15x, Agaricus muscarius 15x, Allium cepa 15x, Allium sativum 15x, Antimonium crudum 15x, Arsenicum album 15x, Baptisia tinctoria 15x, Bovista 15x, Caffeinum 15x, Capsicum annuum 15x, Cinchona officinalis 15x, Cinnamomum 15x, Coccus cacti 15x, Cynara scolymus 15x, Fragaria vesca 15x, Gelsemium sempervirens 15x, Histaminum hydrochloricum 15x, Ipecacuanha 15x, Jequerity 15x, Juglans regia 15x, Lachesis mutus 15x, Ledum palustre 15x, Lycopodium clavatum 15x, Mentha piperita 15x, Natrum muriaticum 15x, Nux moschata 15x, Ova tosta 15x, Phosphorus 15x, Podophyllum peltatum 15x, Pulsatilla 15x, Rhus toxicodendron 15x, Saccharinum 15x, Saccharum lactis 15x, Sepia 15x, Sulphur 15x, Thiosinaminum 15x, Urtica urens 15x, Ustilago maidis 15x, Zingiber officinale 15x, Anacardium occidentale 16x, Ascorbicum acidum 16x, Astacus fluviatilis 16x, Glycyrrhiza glabra 16x, Lycopersicum esculentum 16x, Natrum nitricum 16x, Saccharum officinale 16x, Sinapis nigra 16x, Solanum nigrum 16x, Solanum tuberosum 16x, Torula cerevisiae 16x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as itching, swelling, headaches, indigestion, vomiting and cramping.

INACTIVE INGREDIENT SECTION

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

QUESTIONS SECTION

newtonlabs.net - Questions? 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

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
Since 1987

NDC#
55714-2544-1

Food Additives

Formulated for associated symptoms such as itching, swelling, headaches, indigestion, vomiting and cramping.

1 FL OZ (30 ML)

Directions: Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) as needed or as directed by a health professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

Active Ingredients: Equal parts of Iris vers. 6x, Solidago 6x, Aconitum nap. 15x, Agaricus musc. 15x, Allium cepa 15x, Allium sat. 15x, Antimon. crud. 15x, Arsenicum alb. 15x, Baptisia 15x, Bovista 15x, Caffeinum 15x, Capsicum 15x, Cinchona 15x, Cinnamomum 15x, Coccus 15x, Cynara 15x, Frageria 15x, Gelsemium 15x, Histaminum hydrochloricum 15x, Ipecac. 15x, Jequirity 15x, Juglans reg. 15x, Lachesis 15x, Ledum 15x, Lycopodium 15x, Mentha pip. 15x, Nat. mur. 15x, Nux mosch. 15x, Ova tosta 15x, Phos. 15x, Podoph. pelt. 15x, Pulsatilla 15x, Rhus tox. 15x, Saccharinum 15x, Sac. lac. 15x, Sepia 15x, Sulphur 15x, Thiosinaminum 15x, Urtica ur. 15x, Ustilago maidis 15x., Zingiber 15x, Anacard. occ. 16x, Ascorbicum ac. 16x, Astacus 16x, Glycyrrhiza 16x, Lycopersicum 16x, Nat. nitricum 16x, Saccharum off. 16x, Sinapis nig. 16x, Solanum nig. 16x, Solanum tub. 16x, Torula cerevisiae 16x.

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

Stock# **N058** Lot#

FOOD ADDITIVES

iris versicolor, solidago virgaurea, aconitum napellus, agaricus muscarius, allium cepa, allium sativum, antimonium crudum, arsenicum album, baptisia tinctoria, bovista, caffeinum, capsicum annuum, cinchona officinalis, cinnamomum, coccus cacti, cynara scolymus, fragaria vesca, gelsemium sempervirens, histaminum hydrochloricum, ipecacuanha, jequerity, juglans regia, lachesis mutus, ledum palustre, lycopodium clavatum, mentha piperita, natrum muriaticum, nux moschata, liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2544
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
EGG SHELL, COOKED (UNII: 24HBF856C8) (EGG SHELL, COOKED - UNII:24HBF856C8)	EGG SHELL, COOKED	15 [hp_X] in 1 mL
LYCOPODIUM CLAVATUM SPORE (UNII: C88 X29 Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88 X29 Y479)	LYCOPODIUM CLAVATUM SPORE	15 [hp_X] in 1 mL
RHODODENDRON TOMENTOSUM LEAFY TWIG (UNII: 877L0 1IZ0P) (RHODODENDRON TOMENTOSUM LEAFY TWIG - UNII:877L0 1IZ0P)	RHODODENDRON TOMENTOSUM LEAFY TWIG	15 [hp_X] in 1 mL
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	16 [hp_X] in 1 mL
BLACK MUSTARD SEED (UNII: 8LTY55LQ8D) (BLACK MUSTARD SEED - UNII:8LTY55LQ8D)	BLACK MUSTARD SEED	16 [hp_X] in 1 mL
SOLANUM NIGRUM WHOLE (UNII: 0FMD6 WV47M) (SOLANUM NIGRUM WHOLE - UNII:0FMD6 WV47M)	SOLANUM NIGRUM WHOLE	16 [hp_X] in 1 mL
ANACARDIUM OCCIDENTALE FRUIT (UNII: 4A10JR4E7E) (ANACARDIUM OCCIDENTALE FRUIT - UNII:4A10JR4E7E)	ANACARDIUM OCCIDENTALE FRUIT	16 [hp_X] in 1 mL
SOLANUM LYCOPERSICUM (UNII: 0243Q4990L) (SOLANUM LYCOPERSICUM - UNII:0243Q4990L)	SOLANUM LYCOPERSICUM	16 [hp_X] in 1 mL
SODIUM NITRITE (UNII: M0KG633D4F) (NITRITE ION - UNII:J39976L608)	SODIUM NITRITE	16 [hp_X] in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	15 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	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
ALLYLTHIOUREA (UNII: 706IDJ14B7) (ALLYLTHIOUREA - UNII:706IDJ14B7)	ALLYLTHIOUREA	15 [hp_X] in 1 mL
IRIS VERSICOLOR ROOT (UNII: X43D4L3DQC) (IRIS VERSICOLOR ROOT - UNII:X43D4L3DQC)	IRIS VERSICOLOR ROOT	6 [hp_X] in 1 mL
IPECAC (UNII: 62I3C8233L) (IPECAC - UNII:62I3C8233L)	IPECAC	15 [hp_X] in 1 mL
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	15 [hp_X] in 1 mL
AMANITA MUSCARIA FRUITING BODY (UNII: DIF093I037) (AMANITA MUSCARIA FRUITING BODY - UNII:DIF093I037)	AMANITA MUSCARIA FRUITING BODY	15 [hp_X] in 1 mL
ONION (UNII: 492225Q21H) (ONION - UNII:492225Q21H)	ONION	15 [hp_X] in 1 mL
GARLIC (UNII: V1V998DC17) (GARLIC - UNII:V1V998DC17)	GARLIC	15 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	15 [hp_X] in 1 mL
SACCHARIN (UNII: FST467XS7D) (SACCHARIN - UNII:FST467XS7D)	SACCHARIN	15 [hp_X] in 1 mL
ANTIMONY TRISULFIDE (UNII: F79059A38U) (ANTIMONY CATION (3+) - UNII:069647RPT5)	ANTIMONY TRISULFIDE	15 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	15 [hp_X] in 1 mL
BAPTISIA TINCTORIA ROOT (UNII: 5EF0HWI5WU) (BAPTISIA TINCTORIA ROOT - UNII:5EF0HWI5WU)	BAPTISIA TINCTORIA ROOT	15 [hp_X] in 1 mL
LYCOPERDON UTRIFORME FRUITING BODY (UNII: K2A74U428F) (LYCOPERDON UTRIFORME FRUITING BODY - UNII:K2A74U428F)	LYCOPERDON UTRIFORME FRUITING BODY	15 [hp_X] in 1 mL
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	15 [hp_X] in 1 mL
CAPSICUM (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)	CAPSICUM	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

CINNAMON (UNII: 5S29HWU6QB) (CINNAMON - UNII:5S29HWU6QB)	CINNAMON	15 [hp_X] in 1 mL
PROTORTONIA CACTI (UNII: LZB7TFX1LT) (PROTORTONIA CACTI - UNII:LZB7TFX1LT)	PROTORTONIA CACTI	15 [hp_X] in 1 mL
CYNARA SCOLYMUS LEAF (UNII: B71UA545DE) (CYNARA SCOLYMUS LEAF - UNII:B71UA545DE)	CYNARA SCOLYMUS LEAF	15 [hp_X] in 1 mL
ALPINE STRAWBERRY (UNII: CG6IX3GCMU) (ALPINE STRAWBERRY - UNII:CG6IX3GCMU)	ALPINE STRAWBERRY	15 [hp_X] in 1 mL
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	15 [hp_X] in 1 mL
HISTAMINE DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	15 [hp_X] in 1 mL
SOLIDAGO VIRGAUREA FLOWERING TOP (UNII: 5405K23S50) (SOLIDAGO VIRGAUREA FLOWERING TOP - UNII:5405K23S50)	SOLIDAGO VIRGAUREA FLOWERING TOP	6 [hp_X] in 1 mL
URTICA URENS (UNII: IHN2NQ5OF9) (URTICA URENS - UNII:IHN2NQ5OF9)	URTICA URENS	15 [hp_X] in 1 mL
GINGER (UNII: C5529G5JPQ) (GINGER - UNII:C5529G5JPQ)	GINGER	15 [hp_X] in 1 mL
SUCROSE (UNII: C151H8M554) (SUCROSE - UNII:C151H8M554)	SUCROSE	16 [hp_X] in 1 mL
MENTHA PIPERITA (UNII: 79M2M2UDA9) (MENTHA PIPERITA - UNII:79M2M2UDA9)	MENTHA PIPERITA	15 [hp_X] in 1 mL
ABRUS PRECATORIUS SEED (UNII: 3OM8I6L7CD) (ABRUS PRECATORIUS SEED - UNII:3OM8I6L7CD)	ABRUS PRECATORIUS SEED	15 [hp_X] in 1 mL
JUGLANS REGIA LEAF (UNII: 85HKB87105) (JUGLANS REGIA LEAF - UNII:85HKB87105)	JUGLANS REGIA LEAF	15 [hp_X] in 1 mL
USTILAGO MAYDIS (UNII: 4K7Z7K7SWG) (USTILAGO MAYDIS - UNII:4K7Z7K7SWG)	USTILAGO MAYDIS	15 [hp_X] in 1 mL
LACHESIS MUTA VENOM (UNII: VSW71SS07I) (LACHESIS MUTA VENOM - UNII:VSW71SS07I)	LACHESIS MUTA VENOM	15 [hp_X] in 1 mL
NUTMEG (UNII: AEE24M3MQ9) (NUTMEG - UNII:AEE24M3MQ9)	NUTMEG	15 [hp_X] in 1 mL
PODOPHYLLUM (UNII: 2S713A4VP3) (PODOPHYLLUM - UNII:2S713A4VP3)	PODOPHYLLUM	15 [hp_X] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	15 [hp_X] in 1 mL
ASTACUS ASTACUS (UNII: V0551986XQ) (ASTACUS ASTACUS - UNII:V0551986XQ)	ASTACUS ASTACUS	16 [hp_X] in 1 mL
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H) (GLYCYRRHIZA GLABRA - UNII:2788Z9758H)	GLYCYRRHIZA GLABRA	16 [hp_X] in 1 mL
SOLANUM TUBEROSUM (UNII: 2A8I57T4MX) (SOLANUM TUBEROSUM - UNII:2A8I57T4MX)	SOLANUM TUBEROSUM	16 [hp_X] in 1 mL
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H) (SACCHAROMYCES CEREVISIAE - UNII:978D8U419H)	SACCHAROMYCES CEREVISIAE	16 [hp_X] in 1 mL
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G) (ANHYDROUS LACTOSE - UNII:3SY5LH9PMK)	LACTOSE, UNSPECIFIED FORM	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

Inactive Ingredients

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

Packaging

Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2544-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	07/01/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/01/2019	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment			
Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-2544)

Revised: 11/2020

Newton Laboratories, Inc.