

**DIARRHEA- aesculus hippocastanum, juglans regia, valeriana officinalis, aconitum napellus, argentum nitricum, arsenicum album, baptisia tinctoria, bryonia, carbo vegetabilis, chamomilla, cinchona officinalis, collinsonia canadensis, colocynthis, elaterium, gelsemium sempervirens, ipecacuanha, iris versicolor, lycopodium clavatum, magnesia carbonica, phosphorus, podophyllum peltatum, rheum, sulphur, tabacum, vaccinium myrtillus 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.

Diarrhea 1525L

INDICATIONS AND USAGE SECTION

Formulated for associated symptoms such as loose or liquid stools, cramping, gas, nausea, irritation and fatigue.

DOSAGE & ADMINISTRATION SECTION

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

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Aesculus hippocastanum 6x, Juglans regia 6x, Valeriana officinalis 6x, Aconitum napellus 15x, Argentum nitricum 15x, Arsenicum album 15x, Baptisia tinctoria 15x, Bryonia 15x, Carbo vegetabilis 15x, Chamomilla 15x, Cinchona officinalis 15x, Collinsonia canadensis 15x, Colocynthis 15x, Elaterium 15x, Gelsemium sempervirens 15x, Ipecacuanha 15x, Iris versicolor 15x, Lycopodium clavatum 15x, Magnesia carbonica 15x, Phosphorus 15x, Podophyllum peltatum 15x, Rheum 15x, Sulphur 15x, Tabacum 15x, Vaccinium myrtillus 15x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as loose or liquid stools, cramping, gas, nausea, irritation and fatigue.

INACTIVE INGREDIENT SECTION

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

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.

PACKAGE LABEL

The image shows the front and side of a Newton Homeopathics Kids Diarrhea product box. The front panel is teal with yellow and white text. The top left features the Newton Homeopathics Kids logo with a butterfly. Below the logo is the NDC number 55714-1525-1. The product name "Diarrhea" is prominently displayed in a large, bold, brown font. Below the name, it states "Formulated for associated symptoms such as loose or liquid stools, cramping, gas, nausea, irritation and fatigue." At the bottom of the front panel, it indicates "1 FL OZ (30 ML)". The side panel is yellow and contains the website "newtonlabs.net", a phone number "800.448.7256", and a warning: "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." The back panel is yellow and contains the "Directions" (Children, ages 0 to 11, give 3 drops by mouth (ages 12 and up, give 6 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 Aesculus hipp. 6x, Juglans reg. 6x, Valeriana 6x, Aconitum nap. 15x, Arg. nit. 15x, Arsenicum alb. 15x, Baptisia 15x, Bryonia 15x, Carbo veg. 15x, Chamomilla 15x, Cinchona 15x, Collinsonia 15x, Colocynthis 15x, Elaterium 15x, Gelsemium 15x, Ipecac. 15x, Iris vers. 15x, Lycopodium 15x, Mag. carb. 15x, Phos. 15x, Podoph. pelt. 15x, Rheum 15x, Sulphur 15x, Tabacum 15x, Vaccinium 15x.), "Inactive Ingredients" (USP Purified water; USP Gluten-free, non-GMO, organic cane alcohol 20%), and the stock and lot numbers "Stock# F031 Lot#".

DIARRHEA

aesculus hippocastanum, juglans regia, valeriana officinalis, aconitum napellus, argentum nitricum, arsenicum album, baptisia tinctoria, bryonia, carbo vegetabilis, chamomilla, cinchona officinalis, collinsonia canadensis, colocynthis, elaterium, gelsemium sempervirens, ipecacuanha, iris versicolor, lycopodium clavatum, magnesia carbonica, phosphorus, podophyllum peltatum, rheum, sulphur, tabacum, vaccinium myrtillus liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-1525
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HORSE CHESTNUT (UNII: 3C18L6RJAZ) (HORSE CHESTNUT - UNII:3C18L6RJAZ)	HORSE CHESTNUT	6 [hp_X] in 1 mL
CITRULLUS COLOCYNTHIS FRUIT PULP (UNII: 23HB2AOH17) (CITRULLUS	CITRULLUS COLOCYNTHIS	15 [hp_X]

COLOCYNTHIS FRUIT PULP - UNII:23H32AOH17)	FRUIT PULP	in 1 mL
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	6 [hp_X] in 1 mL
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	15 [hp_X] in 1 mL
SILVER NITRATE (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A)	SILVER NITRATE	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
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	15 [hp_X] in 1 mL
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10) (ACTIVATED CHARCOAL - UNII:2P3VWU3H10)	ACTIVATED CHARCOAL	15 [hp_X] in 1 mL
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	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
COLLINSONIA CANADENSIS ROOT (UNII: O2630F3XDR) (COLLINSONIA CANADENSIS ROOT - UNII:O2630F3XDR)	COLLINSONIA CANADENSIS ROOT	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
IPECAC (UNII: 62I3C8233L) (IPECAC - UNII:62I3C8233L)	IPECAC	15 [hp_X] in 1 mL
IRIS VERSICOLOR ROOT (UNII: X43D4L3DQC) (IRIS VERSICOLOR ROOT - UNII:X43D4L3DQC)	IRIS VERSICOLOR ROOT	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
MAGNESIUM CARBONATE (UNII: 0E53J927NA) (CARBONATE ION - UNII:7UJQ50PE7D)	MAGNESIUM CARBONATE	15 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	15 [hp_X] in 1 mL
PODOPHYLLUM (UNII: 2S713A4VP3) (PODOPHYLLUM - UNII:2S713A4VP3)	PODOPHYLLUM	15 [hp_X] in 1 mL
RHEUM OFFICINALE ROOT (UNII: A47JP5ZG9M) (RHEUM OFFICINALE ROOT - UNII:A47JP5ZG9M)	RHEUM OFFICINALE ROOT	15 [hp_X] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	15 [hp_X] in 1 mL
TOBACCO LEAF (UNII: 6YR2608RSU) (TOBACCO LEAF - UNII:6YR2608RSU)	TOBACCO LEAF	15 [hp_X] in 1 mL
BILBERRY (UNII: 9P2U39H18W) (BILBERRY - UNII:9P2U39H18W)	BILBERRY	15 [hp_X] in 1 mL
ECBALLIUM ELATERIUM FRUIT (UNII: 8P8HWT6ZWC) (ECBALLIUM ELATERIUM FRUIT - UNII:8P8HWT6ZWC)	ECBALLIUM ELATERIUM FRUIT	15 [hp_X] in 1 mL
JUGLANS REGIA LEAF (UNII: 85HKB87105) (JUGLANS REGIA LEAF - UNII:85HKB87105)	JUGLANS REGIA LEAF	6 [hp_X] in 1 mL

Inactive Ingredients

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

Packaging

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-1525-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	01/01/2019	

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

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment			
Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-1525)

Revised: 1/2020

Newton Laboratories, Inc.