

CONSTIPATION- echinacea, iris versicolor, phytolacca decandra, taraxacum officinale, abies nigra, aesculus hippocastanum, aloe, alumina, bryonia, carbo vegetabilis, chelidonium majus, collinsonia canadensis, graphite, hydrastis canadensis 15x, kali carbonicum 15x, lycopodium clavatum 15x, magnesia muriatica 15x, mezereum, nux vomica, podophyllum peltatum, rhamnus purshiana, sanicula, selenium metallicum, sepia, silicea, tabacum, veratrum album, zincum metallicum 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.

Constipation 1523L

INDICATIONS AND USAGE SECTION

Formulated for associated symptoms such as difficult elimination, hard stools, pain, tenderness, pressure and irritability.

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 Echinacea 6x, Iris versicolor 6x, Phytolacca decandra 6x, Taraxacum officinale 6x, Abies nigra 15x, Aesculus hippocastanum 15x, Aloe 15x, Alumina 15x, Bryonia 15x, Carbo vegetabilis 15x, Chelidonium majus 15x, Collinsonia canadensis 15x, Graphites 15x, Hydrastis canadensis 15x, Kali carbonicum 15x, Lycopodium clavatum 15x, Magnesia muriatica 15x, Mezereum 15x, Nux vomica 15x, Podophyllum peltatum 15x, Rhamnus purshiana 15x, Sanicula 15x, Selenium metallicum 15x, Sepia 15x, Silicea 15x, Tabacum 15x, Veratrum album 15x, Zincum metallicum 15x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as difficult elimination, hard stools, pain, tenderness, pressure and irritability.

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

newtonlabs.net ~ Questions? 800.448.7256
Newton Laboratories, Inc. FDA Est #1051203 • Compers, 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
Kids

NDC #
55714-1523-1

Constipation

Formulated for associated symptoms such as difficult elimination, hard stools, pain, tenderness, pressure and irritability.

1 FL OZ (30 ML)

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 Echinacea 6x, Iris vers. 6x, Phytolacca 6x, Taraxacum 6x, Abies nig. 15x, Aesculus hipp. 15x, Aloe 15x, Alumina 15x, Bryonia 15x, Carbo veg. 15x, Chelidonium maj. 15x, Collinsonia 15x, Graphites 15x, Hydrastis 15x, Kali carb. 15x, Lycopodium 15x, Mag. mur. 15x, Mezereum 15x, Nux vom. 15x, Podoph. pelt. 15x, Rhamnus pursh. 15x, Sanicula 15x, Selenium 15x, Sepia 15x, Silicea 15x, Tabacum 15x, Veratrum alb. 15x, Zinc. met. 15x.

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

Stock# F008 Lot#

CONSTIPATION

echinacea, iris versicolor, phytolacca decandra, taraxacum officinale, abies nigra, aesculus hippocastanum, aloe, alumina, bryonia, carbo vegetabilis, chelidonium majus, collinsonia canadensis, graphite, hydrastis canadensis 15x, kali carbonicum 15x, lycopodium clavatum 15x, magnesia muriatica 15x, mezereum, nux vomica, podophyllum peltatum, rhamnus purshiana, sanicula, selenium metallicum, sepia, silicea, tabacum, veratrum album, zincum metallicum liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-1523
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	15 [hp_X] in 1 mL
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	6 [hp_X] in 1 mL
COLLINSONIA CANADENSIS ROOT (UNII: O2630F3XDR) (COLLINSONIA CANADENSIS ROOT - UNII:O2630F3XDR)	COLLINSONIA CANADENSIS ROOT	15 [hp_X] in 1 mL
PHYTOLACCA AMERICANA ROOT (UNII: 11E6VI8VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6VI8VEG)	PHYTOLACCA AMERICANA ROOT	6 [hp_X] in 1 mL
TARAXACUM OFFICINALE (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)	TARAXACUM OFFICINALE	6 [hp_X] in 1 mL
PICEA MARIANA RESIN (UNII: 71AOV0W131) (PICEA MARIANA RESIN - UNII:71AOV0W131)	PICEA MARIANA RESIN	15 [hp_X] in 1 mL
HORSE CHESTNUT (UNII: 3C18L6RJAZ) (HORSE CHESTNUT - UNII:3C18L6RJAZ)	HORSE CHESTNUT	15 [hp_X] in 1 mL
ALOE (UNII: V5VD430YW9) (ALOE - UNII:V5VD430YW9)	ALOE	15 [hp_X] in 1 mL
ALUMINUM OXIDE (UNII: LM26O6933) (ALUMINUM OXIDE - UNII:LM26O6933)	ALUMINUM OXIDE	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
CHELIDONIUM MAJUS (UNII: 7E889U5RNN) (CHELIDONIUM MAJUS - UNII:7E889U5RNN)	CHELIDONIUM MAJUS	15 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	15 [hp_X] in 1 mL
POTASSIUM CARBONATE (UNII: BQN1B9B9HA) (CARBONATE ION - UNII:7UJQ5OPE7D)	POTASSIUM CARBONATE	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 CHLORIDE (UNII: 02F3473H9O) (CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	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
PODOPHYLLUM (UNII: 2S713A4VP3) (PODOPHYLLUM - UNII:2S713A4VP3)	PODOPHYLLUM	15 [hp_X] in 1 mL
KRAMERIA LAPPACEA ROOT (UNII: P29ZH1A35Z) (KRAMERIA LAPPACEA ROOT - UNII:P29ZH1A35Z)	KRAMERIA LAPPACEA ROOT	15 [hp_X] in 1 mL
SANICULA EUROPAEA LEAF (UNII: JYZ6110L9I) (SANICULA EUROPAEA LEAF - UNII:JYZ6110L9I)	SANICULA EUROPAEA LEAF	15 [hp_X] in 1 mL
SELENIUM (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	15 [hp_X] in 1 mL
TOBACCO LEAF (UNII: 6YR2608RSU) (TOBACCO LEAF - UNII:6YR2608RSU)	TOBACCO LEAF	15 [hp_X] in 1 mL
VERATRUM ALBUM ROOT (UNII: QNS6W5US1Z) (VERATRUM ALBUM ROOT - UNII:QNS6W5US1Z)	VERATRUM ALBUM ROOT	15 [hp_X] in 1 mL
GRAPHITE (UNII: 4QQN74LH4O) (GRAPHITE - UNII:4QQN74LH4O)	GRAPHITE	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

Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
ALCOHOL (UNII: 3K9958V90M)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-1523-1	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(55714-1523)