

**CONSTIPATION - abies nig., aesculus hipp., aloe, alumina, bryonia, carbo veg., chelidonium majus, collinsonia, graphites, hydrastis, kali carb., lycopodium, mag. mur., mezereum, nux vom., podoph. pelt., rhamnus purshiana, sanicula, selenium, sepia, silicea, tabacum, veratrum alb., zinc. met., echinacea, iris versicolor, phytolacca, taraxacum 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

INDICATIONS & USAGE SECTION

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

DOSAGE & ADMINISTRATION SECTION

Directions: ORAL USE ONLY - SHAKE WELL. Children, ages 0 to 11, give 3 drops orally (ages 12 and up, give 6 drops) as needed or as directed by a healthcare professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Abies nig. 15x, Aesculus hipp. 15x, Aloe 15x, Alumina 15x, Bryonia 15x, Carbo veg. 15x, Chelidonium majus 15x, Collinsonia 15x, Graphites 15x, Hydrastis 15x, Kali carb. 15x, Lycopodium 15x, Mag. mur. 15x, Mezereum 15x, Nux vom. 15x, Podoph. pelt. 15x, Rhamnus purshiana 15x, Sanicula 15x, Selenium 15x, Sepia 15x, Silicea 15x, Tabacum 15x, Veratrum alb. 15x, Zinc.met. 15x, Echinacea 3x, Iris versicolor 3x, Phytolacca 3x, Taraxacum 3x.

OTC - PURPOSE SECTION

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

INACTIVE INGREDIENT SECTION

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

QUESTIONS SECTION

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

WARNINGS SECTION

Warning: Do not use if tamper - evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.

OTC - PREGNANCY OR BREAST FEEDING SECTION

Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

PACKAGE LABEL

Warnings: Do not use if tamper-evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.

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 Newton Laboratories, Inc. FDA Est# 1051203 • Conway, GA 30012
Questions? 1.800.448.7256



NDC#
55714-1505-1

Constipation

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

1 fl oz (29.57 ml)

Directions: ORAL USE ONLY - SHAKE WELL.
 Children, ages 0 to 11, give 3 drops orally (ages 12 and up, give 6 drops) as needed or as directed by a healthcare professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

Active Ingredients: Abies nig. 15x, Aesculus hipp. 15x, Aloe 15x, Alumina 15x, Bryonia 15x, Carbo veg. 15x, Chelidonium majus 15x, Collinsonia 15x, Graphites 15x, Hydrastis 15x, Kali carb. 15x, Lycopodium 15x, Mag. mur. 15x, Mezereum 15x, Nux vom. 15x, Podoph. pelt. 15x, Rhamnus purshiana 15x, Sanicula 15x, Selenium 15x, Sepia 15x, Silicea 15x, Tabacum 15x, Veratrum alb. 15x, Zinc. met. 15x, Echinacea 3x, Iris versicolor 3x, Phytolacca 3x, Taraxacum 3x

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

Stock# F008 Lot#

CONSTIPATION

abies nig., aesculus hipp., aloe, alumina, bryonia, carbo veg., chelidonium majus, collinsonia, graphites, hydrastis, kali carb., lycopodium, mag. mur., mezereum, nux vom., podoph. pelt., rhamnus purshiana, sanicula, selenium, sepia, silicea, tabacum, veratrum alb., zinc. met., echinacea, iris versicolor, phytolacca, taraxacum liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-1505
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
Collinsonia Canadensis Root (UNII: O2630F3XDR) (Collinsonia Canadensis Root - UNII:O2630F3XDR)	Collinsonia Canadensis Root	15 [hp_X] in 1 mL
Graphite (UNII: 4QQN74LH4O) (Graphite - UNII:4QQN74LH4O)	Graphite	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) (Magnesium Cation - UNII:T6V3LHY838)	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
Frangula Purshiana Bark (UNII: 4VBP01X99F) (Frangula Purshiana Bark - UNII:4VBP01X99F)	Frangula Purshiana Bark	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
Zinc (UNII: J41CSQ7QDS) (Zinc - UNII:J41CSQ7QDS)	Zinc	15 [hp_X] in 1 mL
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	3 [hp_X] in 1 mL
Iris Versicolor Root (UNII: X43D4L3DQC) (Iris Versicolor Root - UNII:X43D4L3DQC)	Iris Versicolor Root	3 [hp_X] in 1 mL
Phytolacca Americana Root (UNII: 11E6VI8VEG) (Phytolacca Americana Root - UNII:11E6VI8VEG)	Phytolacca Americana Root	3 [hp_X] in 1 mL
Taraxacum Officinale (UNII: 39981FM375) (Taraxacum Officinale - UNII:39981FM375)	Taraxacum Officinale	3 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Alcohol (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-1505-1	29.57 mL in 1 BOTTLE, GLASS		
2	NDC:55714-1505-2	59.14 mL in 1 BOTTLE, GLASS		

3	NDC:55714-1505-0	.5 mL 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(55714-1505)

Revised: 3/2011

Newton Laboratories, Inc.