

**TEETHING - COLIC - aconitum nap., apis mel., baptisia, belladonna, borax, bryonia, calc. carb., calc. phos., chamomilla, chelidonium majus, coffea cruda, collinsonia, colocynthis, kreosotum, mag.phos., nux vom., podoph. pelt., rheum, scutellaria lateriflora, silicea, terebinthina, zingiber, valeriana 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.

Teething - Colic

INDICATIONS & USAGE SECTION

Teething - Colic Formulated for associated symptoms such as inconsolable crying, painful and swollen gums, sleeplessness and digestive discomfort.

DOSAGE & ADMINISTRATION SECTION

Directions: Children, ages 0 to 11, give 3 pellets orally (ages 12 and up, give 6 pellets) as needed or as directed by a healthcare professional. Under age 2, crush or dissolve pellets in purified water. Sensitive persons begin with 1 pellet and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Aconitum nap. 10x, Apis mel. 10x, Baptisia 10x, Belladonna 10x, Borax 10x, Bryonia 10x, Calc. carb. 10x, Calc. phos. 10x, Chamomilla 10x, Chelidonium majus 10x, Coffea cruda 10x, Collinsonia 10x, Colocynthis 10x, Kreosotum 10x, Mag. phos. 10x, Nux vom. 10x, Podoph. pelt. 10x, Rheum 10x, Scutellaria lateriflora 10x, Silicea 10x, Terebinthina 10x, Zingiber 10x, Chamomilla 3x, Valeriana 3x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as inconsolable crying, painful and swollen gums, sleeplessness and digestive discomfort.

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: 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

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

NEWTON
homeopathics
for Kids
Nurturing Naturally Since 1987™

NDC#
55714-1709-1

Teething ~ Colic

Formulated for associated symptoms such as inconsolable crying, painful and swollen gums, sleeplessness and digestive discomfort.

1 oz (28.35 g)

Directions: Children, ages 0 to 11, give 3 pellets orally (ages 12 and up, give 6 pellets) as needed or as directed by a healthcare professional. Under age 2, crush or dissolve pellets in purified water. Sensitive persons begin with 1 pellet and gradually increase to full dose.

Active Ingredients: Aconitum nap. 10x, Apis mel. 10x, Baptisia 10x, Belladonna 10x, Borax 10x, Bryonia 10x, Calc. carb. 10x, Calc. phos. 10x, Chamomilla 10x, Chelidonium majus 10x, Coffea cruda 10x, Collinsonia 10x, Colocynthis 10x, Kreosotum 10x, Mag. phos. 10x, Nux vom. 10x, Podoph. pelt. 10x, Rheum 10x, Scutellaria lateriflora 10x, Silicea 10x, Terebinthina 10x, Zingiber 10x, Chamomilla 3x, Valeriana 3x.

Inactive Ingredients: Gluten-free, non-GMO, beet-derived sucrose pellets.

Stock# **F026** Lot#

TEETHING - COLIC

aconitum nap., apis mel., baptisia, belladonna, borax, bryonia, calc. carb., calc. phos., chamomilla, chelidonium majus, coffea cruda, collinsonia, colocynthis, kreosotum, mag.phos., nux vom., podoph. pelt., rheum, scutellarialateriflora, silicea, terebinthina, zingiber, valeriana pellet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-1709
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Aconitum Napellus (UNII: U0NQ8555JD) (Aconitum Napellus - UNII:U0NQ8555JD)	Aconitum Napellus	10 [hp_X] in 1 g
Apis Mellifera (UNII: 7S82P3R43Z) (Apis Mellifera - UNII:7S82P3R43Z)	Apis Mellifera	10 [hp_X] in 1 g
Baptisia Tinctoria (UNII: 5K1UO2888Y) (Baptisia Tinctoria - UNII:5K1UO2888Y)	Baptisia Tinctoria	10 [hp_X] in 1 g
Atropa Belladonna (UNII: WQZ3G9PF0H) (Atropa Belladonna - UNII:WQZ3G9PF0H)	Atropa Belladonna	10 [hp_X] in 1 g

Sodium Borate (UNII: 91MBZ8H3QO) (Borate Ion - UNII:44OAE30D22)	Sodium Borate	10 [hp_X] in 1 g
Bryonia Alba Root (UNII: T7J046YI2B) (Bryonia Alba Root - UNII:T7J046YI2B)	Bryonia Alba Root	10 [hp_X] in 1 g
Oyster Shell Calcium Carbonate, Crude (UNII: 2E32821G6I) (Oyster Shell Calcium Carbonate, Crude - UNII:2E32821G6I)	Oyster Shell Calcium Carbonate, Crude	10 [hp_X] in 1 g
Tribasic Calcium Phosphate (UNII: 91D9GV0Z28) (Calcium Cation - UNII:2M83C4R6ZB)	Calcium Cation	10 [hp_X] in 1 g
Matricaria Recutita (UNII: G0R4UBI2ZZ) (Matricaria Recutita - UNII:G0R4UBI2ZZ)	Matricaria Recutita	10 [hp_X] in 1 g
Chelidonium Majus (UNII: 7E889U5RNN) (Chelidonium Majus - UNII:7E889U5RNN)	Chelidonium Majus	10 [hp_X] in 1 g
Arabica Coffee Bean (UNII: 3SW678MX72) (Arabica Coffee Bean - UNII:3SW678MX72)	Arabica Coffee Bean	10 [hp_X] in 1 g
Collinsonia Canadensis Root (UNII: O2630F3XDR) (Collinsonia Canadensis Root - UNII:O2630F3XDR)	Collinsonia Canadensis Root	10 [hp_X] in 1 g
Citrullus Colocynthis Fruit Pulp (UNII: 23H32AOH17) (Citrullus Colocynthis Fruit Pulp - UNII:23H32AOH17)	Citrullus Colocynthis Fruit Pulp	10 [hp_X] in 1 g
Wood Creosote (UNII: 3JYG22FD73) (Wood Creosote - UNII:3JYG22FD73)	Wood Creosote	10 [hp_X] in 1 g
Magnesium Phosphate, Dibasic Trihydrate (UNII: HF539G9L3Q) (Magnesium Cation - UNII:T6V3LHY838)	Magnesium Phosphate, Dibasic Trihydrate	10 [hp_X] in 1 g
Strychnos Nux-vomica Seed (UNII: 269XH13919) (Strychnos Nux-vomica Seed - UNII:269XH13919)	Strychnos Nux-vomica Seed	10 [hp_X] in 1 g
Podophyllum (UNII: 2S713A4VP3) (Podophyllum - UNII:2S713A4VP3)	Podophyllum	10 [hp_X] in 1 g
Rheum Officinale Root (UNII: A47JP5ZG9M) (Rheum Officinale Root - UNII:A47JP5ZG9M)	Rheum Officinale Root	10 [hp_X] in 1 g
Scutellaria Lateriflora (UNII: 7BP4DH5PDC) (Scutellaria Lateriflora - UNII:7BP4DH5PDC)	Scutellaria Lateriflora	10 [hp_X] in 1 g
Silicon Dioxide (UNII: ETJ7Z6XBU4) (Silicon Dioxide - UNII:ETJ7Z6XBU4)	Silicon Dioxide	10 [hp_X] in 1 g
Turpentine Oil (UNII: C5H0QJ6V7F) (Turpentine Oil - UNII:C5H0QJ6V7F)	Turpentine Oil	10 [hp_X] in 1 g
Ginger (UNII: C5529G5JPQ) (Ginger - UNII:C5529G5JPQ)	Ginger	10 [hp_X] in 1 g
Valerian (UNII: JWF5YAW3QW) (Valerian - UNII:JWF5YAW3QW)	Valerian	3 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
Sucrose (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-1709-1	28.35 g in 1 BOTTLE, GLASS		
2	NDC:55714-1709-2	56.7 g in 1 BOTTLE, GLASS		
3	NDC:55714-1709-0	7.08 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(55714-1709)

Revised: 3/2011

Newton Laboratories, Inc.