

TEETHING-COLIC- chamomilla, valeriana officinalis, aconitum napellus, apis mellifica, baptisia tinctoria, belladonna, borax, bryonia, calcarea carbonica, calcarea phosphorica, chamomilla, chelidonium majus, coffea cruda, collinsonia canadensis, colocynthis, kreosotum, magnesia phosphorica, nux vomica, podophyllum peltatum, rheum, scutellaria lateriflora, silicea, terebinthina, zingiber officinale 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 1730P

INDICATIONS AND USAGE SECTION

Formulated for associated symptoms such as inconsolable crying, painful and swollen gums, sleeplessness and other related symptoms.

DOSAGE & ADMINISTRATION SECTION

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

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Chamomilla 6x, Valeriana officinalis 6x, Aconitum napellus 15x, Apis mellifica 15x, Baptisia tinctoria 15x, Belladonna 15x, Borax 15x, Bryonia 15x, Calcarea carbonica 15x, Calcarea phosphorica 15x, Chamomilla 15x, Chelidonium majus 15x, Coffea cruda 15x, Collinsonia canadensis 15x, Colocynthis 15x, Kreosotum 15x, Magnesia phosphorica 15x, Nux vomica 15x, Podophyllum peltatum 15x, Rheum 15x, Scutellaria lateriflora 15x, Silicea 15x, Terebinthina 15x, Zingiber officinale 15x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as inconsolable crying, painful and swollen gums, sleeplessness and other related symptoms.

INACTIVE INGREDIENT SECTION

Gluten-free, non-GMO, organic beet-derived sucrose (lactose-free) pellets.

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.

PACKAGE LABEL

newtonlabs.net ~ Questions? 800.448.7256
Newton Laboratories, Inc. FDA Est #1051203 • Compens. 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 #
55714-1730-1

**Teething
~Colic**

Formulated for associated symptoms such as inconsolable crying, painful and swollen gums, sleeplessness and other related symptoms.

1 OZ (28 G)

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

Active Ingredients: Equal parts of Chamomilla 6x, Valeriana 6x, Aconitum nap. 15x, Apis mel. 15x, Baptisia 15x, Belladonna 15x, Borax 15x, Bryonia 15x, Calc. carb. 15x, Calc. phos. 15x, Chamomilla 15x, Chelidonium maj. 15x, Coffea cruda 15x, Collinsonia 15x, Colocynthis 15x, Kreosotum 15x, Mag. phos. 15x, Nux vom. 15x, Podoph. pelt. 15x, Rheum 15x, Scutellaria 15x, Silicea 15x, Terebinthina 15x, Zingiber 15x.

Inactive Ingredients: Gluten-free, non-GMO, organic beet-derived sucrose (lactose-free) pellets.

Stock# F026 Lot#

TEETHING-COLIC

chamomilla, valeriana officinalis, aconitum napellus, apis mellifica, baptisia tinctoria, belladonna, borax, bryonia, calcarea carbonica, calcarea phosphorica, chamomilla, chelidonium majus, coffea cruda, collinsonia canadensis, colocynthis, kreosotum, magnesia phosphorica, nux vomica, podophyllum peltatum, rheum, scutellaria lateriflora, silicea, terebinthina, zingiber officinale pellet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-1730
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	6 [hp_X] in 1 g
COLLINSONIA CANADENSIS ROOT (UNII: O2630F3XDR) (COLLINSONIA CANADENSIS ROOT - UNII:O2630F3XDR)	COLLINSONIA CANADENSIS ROOT	15 [hp_X] in 1 g
APIS MELLIFICA (UNII: 7S82D2D42Z) (APIS MELLIFICA - UNII:7S82D2D42Z)	APIS MELLIFICA	15 [hp_X]

AFIS MELLIFERA (UNII: 7302F3R43Z) (AFIS MELLIFERA - UNII:7302F3R43Z)	AFIS MELLIFERA	in 1 g
BAPTISIA TINCTORIA ROOT (UNII: 5EF0HWI5WU) (BAPTISIA TINCTORIA ROOT - UNII:5EF0HWI5WU)	BAPTISIA TINCTORIA ROOT	15 [hp_X] in 1 g
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	15 [hp_X] in 1 g
SODIUM BORATE (UNII: 91MBZ8H3QO) (BORATE ION - UNII:44OAE30D22)	SODIUM BORATE	15 [hp_X] in 1 g
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	15 [hp_X] in 1 g
OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	15 [hp_X] in 1 g
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) (PHOSPHATE ION - UNII:NK08V8K8HR)	TRIBASIC CALCIUM PHOSPHATE	15 [hp_X] in 1 g
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	15 [hp_X] in 1 g
CHELIDONIUM MAJUS (UNII: 7E889U5RNN) (CHELIDONIUM MAJUS - UNII:7E889U5RNN)	CHELIDONIUM MAJUS	15 [hp_X] in 1 g
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	15 [hp_X] in 1 g
WOOD CREOSOTE (UNII: 3JYG22FD73) (WOOD CREOSOTE - UNII:3JYG22FD73)	WOOD CREOSOTE	15 [hp_X] in 1 g
MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE (UNII: HF539G9L3Q) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE	15 [hp_X] in 1 g
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	15 [hp_X] in 1 g
PODOPHYLLUM (UNII: 2S713A4VP3) (PODOPHYLLUM - UNII:2S713A4VP3)	PODOPHYLLUM	15 [hp_X] in 1 g
RHEUM OFFICINALE ROOT (UNII: A47JP5ZG9M) (RHEUM OFFICINALE ROOT - UNII:A47JP5ZG9M)	RHEUM OFFICINALE ROOT	15 [hp_X] in 1 g
SCUTELLARIA LATERIFLORA WHOLE (UNII: 7BP4DH5PDC) (SCUTELLARIA LATERIFLORA WHOLE - UNII:7BP4DH5PDC)	SCUTELLARIA LATERIFLORA WHOLE	15 [hp_X] in 1 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	15 [hp_X] in 1 g
TURPENTINE OIL (UNII: C5H0QJ6V7F) (TURPENTINE OIL - UNII:C5H0QJ6V7F)	TURPENTINE OIL	15 [hp_X] in 1 g
GINGER (UNII: C5529G5JPQ) (GINGER - UNII:C5529G5JPQ)	GINGER	15 [hp_X] in 1 g
CITRULLUS COLOCYNTHIS FRUIT PULP (UNII: 23H32AOH17) (CITRULLUS COLOCYNTHIS FRUIT PULP - UNII:23H32AOH17)	CITRULLUS COLOCYNTHIS FRUIT PULP	15 [hp_X] in 1 g
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	15 [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:55714-1730-1	28 g 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(55714-1730)