

**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 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.*

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**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: 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**

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:** 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

## 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 liquid

### Product Information

|                         |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:55714-1509 |
| 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 mL |
| Apis Mellifera (UNII: 7S82P3R43Z) (Apis Mellifera - UNII:7S82P3R43Z)         | Apis Mellifera     | 10 [hp_X] in 1 mL |
| Baptisia Tinctoria (UNII: 5K1UO2888Y) (Baptisia Tinctoria - UNII:5K1UO2888Y) | Baptisia Tinctoria | 10 [hp_X] in 1 mL |
| Atropa Belladonna (UNII: WQZ3G9PF0H) (Atropa Belladonna - UNII:WQZ3G9PF0H)   | Atropa Belladonna  | 10 [hp_X] in 1 mL |
| Sodium Borate (UNII: 91MBZ8H3QO) (Borate Ion - UNII:44OAE30D22)              | Sodium Borate      | 10 [hp_X] in 1 mL |
| Bryonia Alba Root (UNII: T71046YD2B) (Bryonia Alba Root - UNII:T71046YD2B)   | Bryonia Alba Root  | 10 [hp_X]         |

|   |   |                      |
|---|---|----------------------|
| <b>Biyonia Aida Root</b> (UNII: 179401ZD) (Biyonia Aida Root - UNII:179401ZD)   | Biyonia Aida Root                       | in 1 mL              |
| <b>Oyster Shell Calcium Carbonate, Crude</b> (UNII: 2E32821G6I) (Oyster Shell Calcium Carbonate, Crude - UNII:2E32821G6I) | Oyster Shell Calcium Carbonate, Crude   | 10 [hp_X]<br>in 1 mL |
| <b>Tribasic Calcium Phosphate</b> (UNII: 91D9GV0Z28) (Phosphate Ion - UNII:NK08V8K8HR)                                    | Tribasic Calcium Phosphate              | 10 [hp_X]<br>in 1 mL |
| <b>Matricaria Recutita</b> (UNII: G0R4UBI2ZZ) (Matricaria Recutita - UNII:G0R4UBI2ZZ)                                     | Matricaria Recutita                     | 10 [hp_X]<br>in 1 mL |
| <b>Chelidonium Majus</b> (UNII: 7E889U5RNN) (Chelidonium Majus - UNII:7E889U5RNN)   | Chelidonium Majus                       | 10 [hp_X]<br>in 1 mL |
| <b>Arabica Coffee Bean</b> (UNII: 3SW678MX72) (Arabica Coffee Bean - UNII:3SW678MX72)                                     | Arabica Coffee Bean                     | 10 [hp_X]<br>in 1 mL |
| <b>Collinsonia Canadensis Root</b> (UNII: O2630F3XDR) (Collinsonia Canadensis Root - UNII:O2630F3XDR)                     | Collinsonia Canadensis Root             | 10 [hp_X]<br>in 1 mL |
| <b>Citrullus Colocynthis Fruit Pulp</b> (UNII: 23H32AOH17) (Citrullus Colocynthis Fruit Pulp - UNII:23H32AOH17)           | Citrullus Colocynthis Fruit Pulp        | 10 [hp_X]<br>in 1 mL |
| <b>Wood Creosote</b> (UNII: 3JYG22FD73) (Wood Creosote - UNII:3JYG22FD73)   | Wood Creosote                           | 10 [hp_X]<br>in 1 mL |
| <b>Magnesium Phosphate, Dibasic Trihydrate</b> (UNII: HF539G9L3Q) (Magnesium Cation - UNII:T6V3LHY838)                    | Magnesium Phosphate, Dibasic Trihydrate | 10 [hp_X]<br>in 1 mL |
| <b>Strychnos Nux-vomica Seed</b> (UNII: 269XH13919) (Strychnos Nux-vomica Seed - UNII:269XH13919)                         | Strychnos Nux-vomica Seed               | 10 [hp_X]<br>in 1 mL |
| <b>Podophyllum</b> (UNII: 2S713A4VP3) (Podophyllum - UNII:2S713A4VP3)   | Podophyllum                             | 10 [hp_X]<br>in 1 mL |
| <b>Rheum Officinale Root</b> (UNII: A47JP5ZG9M) (Rheum Officinale Root - UNII:A47JP5ZG9M)                                 | Rheum Officinale Root                   | 10 [hp_X]<br>in 1 mL |
| <b>Scutellaria Lateriflora</b> (UNII: 7BP4DH5PDC) (Scutellaria Lateriflora - UNII:7BP4DH5PDC)                             | Scutellaria Lateriflora                 | 10 [hp_X]<br>in 1 mL |
| <b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4) (Silicon Dioxide - UNII:ETJ7Z6XBU4)   | Silicon Dioxide                         | 10 [hp_X]<br>in 1 mL |
| <b>Turpentine Oil</b> (UNII: C5H0QJ6V7F) (Turpentine Oil - UNII:C5H0QJ6V7F)   | Turpentine Oil                          | 10 [hp_X]<br>in 1 mL |
| <b>Ginger</b> (UNII: C5529G5JPQ) (Ginger - UNII:C5529G5JPQ)   | Ginger                                  | 10 [hp_X]<br>in 1 mL |
| <b>Valerian</b> (UNII: JWF5YAW3QW) (Valerian - UNII:JWF5YAW3QW)   | Valerian                                | 3 [hp_X]<br>in 1 mL  |

## Inactive Ingredients

| Ingredient Name                   | Strength |
|-----------------------------------|----------|
| <b>Alcohol</b> (UNII: 3K9958V90M) |          |

## Packaging

| # | Item Code        | Package Description         | Marketing Start Date | Marketing End Date |
|---|------------------|-----------------------------|----------------------|--------------------|
| 1 | NDC:55714-1509-1 | 29.57 mL in 1 BOTTLE, GLASS |                      |                    |
| 2 | NDC:55714-1509-2 | 59.14 mL in 1 BOTTLE, GLASS |                      |                    |
| 3 | NDC:55714-1509-0 | .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**

| <b>Name</b>               | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|---------------------------|----------------|---------------|----------------------------|
| Newton Laboratories, Inc. |                | 788793610     | MANUFACTURE(55714-1509)    |

Revised: 3/2011

Newton Laboratories, Inc.