

**PAIN SOOTHER - aconitum nap., arg. nit., arnica, bryonia, colchicum, guaiacum, hypericum, kalmia, phosphorus, phytolacca, pulsatilla, rhus toxicodendron, ruta, sarcolacticum ac., sticta, stramonium, hamamelis, 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.*

-----  
**Pain Soother**

**INDICATIONS & USAGE SECTION**

**Pain Soother** Formulated for symptoms associated with bruises, strains and overexertion such as pain, stiffness and inflammation.

**DOSAGE & ADMINISTRATION SECTION**

**Directions: ORAL USE ONLY** - Ages 12 and up, take 6 drops orally (ages 0 to 11, give 3 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. 15x, Arg. nit. 15x, Arnica 15x, Bryonia 15x, Colchicum 15x, Guaiacum 15x, Hypericum 15x, Kalmia latifolia 15x, Phos. 15x, Phytolacca 15x, Pulsatilla 15x, Rhus tox. 15x, Ruta 15x, Sarcolacticum ac. 15x, Sticta 15x, Stramonium 15x, Hamamelis 3x, Phytolacca 3x, Ruta 3x, Taraxacum 3x.

**OTC - PURPOSE SECTION**

Formulated for symptoms associated with bruises, strains and overexertion such as pain, stiffness and inflammation.

**INACTIVE INGREDIENT SECTION**

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

**OTC - 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

## PAIN SOOTHER

aconitum nap., arg. nit., arnica, bryonia, colchicum, guaiacum, hypericum, kalmia, phosphorus, phytolacca, pulsatilla, rhus toxicodendron, ruta, sarcocollinum ac., sticta, stramonium, hamamelis, taraxacum, liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-8008
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Aconitum Napellus (UNII: U0NQ8555JD) (Aconitum Napellus - UNII:U0NQ8555JD)	Aconitum Napellus	15 [hp_X] in 1 mL
Silver Nitrate (UNII: 95IT3W8JZE) (Silver Cation - UNII:57N7B0K90A)	Silver Nitrate	15 [hp_X] in 1 mL
Arnica Montana (UNII: O80TY208ZW) (Arnica Montana - UNII:O80TY208ZW)	Arnica Montana	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
Colchicum Autumnale Bulb (UNII: 993QHL78E6) (Colchicum Autumnale Bulb - UNII:993QHL78E6)	Colchicum Autumnale Bulb	15 [hp_X] in 1 mL

UNII:993QHL78E6)	Cocineum Autumnale Dried	in 1 mL
<b>Guaiac</b> (UNII: 03C8A0DFJ8) (Guaiac - UNII:03C8A0DFJ8)	Guaiac	15 [hp_X] in 1 mL
<b>Hypericum Perforatum</b> (UNII: XK4IUX8MNB) (Hypericum Perforatum - UNII:XK4IUX8MNB)	Hypericum Perforatum	15 [hp_X] in 1 mL
<b>Kalmia Latifolia Leaf</b> (UNII: 79N6542N18) (Kalmia Latifolia Leaf - UNII:79N6542N18)	Kalmia Latifolia Leaf	15 [hp_X] in 1 mL
<b>Phosphorus</b> (UNII: 27YLU75U4W) (Phosphorus - UNII:27YLU75U4W)	Phosphorus	15 [hp_X] in 1 mL
<b>Phytolacca Americana Root</b> (UNII: 11E6VI8VEG) (Phytolacca Americana Root - UNII:11E6VI8VEG)	Phytolacca Americana Root	15 [hp_X] in 1 mL
<b>Pulsatilla Vulgaris</b> (UNII: I76KB35JEV) (Pulsatilla Vulgaris - UNII:I76KB35JEV)	Pulsatilla Vulgaris	15 [hp_X] in 1 mL
<b>Toxicodendron Pubescens Leaf</b> (UNII: 6IO182RP7A) (Toxicodendron Pubescens Leaf - UNII:6IO182RP7A)	Toxicodendron Pubescens Leaf	15 [hp_X] in 1 mL
<b>Ruta Graveolens Flowering Top</b> (UNII: N94C2U587S) (Ruta Graveolens Flowering Top - UNII:N94C2U587S)	Ruta Graveolens Flowering Top	15 [hp_X] in 1 mL
<b>Lactic Acid, L-</b> (UNII: F9S9FFU82N) (Lactic Acid, L- - UNII:F9S9FFU82N)	Lactic Acid, L-	15 [hp_X] in 1 mL
<b>Lobaria Pulmonaria</b> (UNII: D1YM0P5Z2T) (Lobaria Pulmonaria - UNII:D1YM0P5Z2T)	Lobaria Pulmonaria	15 [hp_X] in 1 mL
<b>Datura Stramonium</b> (UNII: G6W4F0V8Z3) (Datura Stramonium - UNII:G6W4F0V8Z3)	Datura Stramonium	15 [hp_X] in 1 mL
<b>Hamamelis Virginiana Root Bark/stem Bark</b> (UNII: T7S323PKJS) (Hamamelis Virginiana Root Bark/stem Bark - UNII:T7S323PKJS)	Hamamelis Virginiana Root Bark/stem Bark	3 [hp_X] in 1 mL
<b>Taraxacum Officinale</b> (UNII: 39981FM375) (Taraxacum Officinale - UNII:39981FM375)	Taraxacum Officinale	3 [hp_X] 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:55714-8008-1	29.57 mL in 1 BOTTLE, GLASS		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/15/2014	

**Labeler** - Newton Laboratories, Inc. (788793610)

**Registrant** - Newton Laboratories, Inc. (788793610)

### Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-8008)

