

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

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**Aches - Pains 2383P**

## **INDICATIONS & USAGE SECTION**

**Aches - Pains:** Formulated for symptoms associated with bruises, strains and overexertion such as pain, stiffness and inflammation.

## **OTC - ACTIVE INGREDIENT SECTION**

**Active Ingredients:** Equal parts of Hamamelis 6x, Phytolacca 6x, Ruta 6x, Taraxacum 6x, Aconitum nap. 15x, Arg. nit. 15x, Arnica 15x, Bryonia 15x, Colchicum 15x, Guaiacum 15x, Hypericum 15x, Kalmia 15x, Phos. 15x, Phytolacca 15x, Pulsatilla 15x, Rhus tox. 15x, Ruta 15x, Sarcolacticum ac. 15x, Sticta 15x, Stramonium 15x.

## **OTC - PURPOSE SECTION**

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

## **INACTIVE INGREDIENT SECTION**

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

## **OTC - QUESTIONS SECTION**

newtonlabs.net ~ **Questions? 800-448-7256**

Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 30013

## **OTC - PREGNANCY OR BREAST FEEDING SECTION**

If **pregnant or breast-feeding**, ask a doctor before use.

## **OTC - KEEP OUT OF REACH OF CHILDREN SECTION**

**Keep out of reach of children.**

## **DOSAGE & ADMINISTRATION SECTION**

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

## **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.

**PACKAGE LABEL**

**newtonlabs.net ~ Questions? 800.448.7256**  
 Newton Laboratories, Inc. FDA Est# 1051203 • Conners, 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** **Since 1987**

NDC# 55714-2383-1

**Aches ~ Pains**

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

**1 OZ (28 G)**

**Directions:** Ages 12 and up, take 6 pellets by mouth (ages 0 to 11, give 3 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 Hamamelis 6x, Phytolacca 6x, Ruta 6x, Taraxacum 6x, Aconitum nap. 15x, Arg. nit. 15x, Arnica 15x, Bryonia 15x, Colchicum 15x, Guaiacum 15x, Hypericum 15x, Kalmia 15x, Phos. 15x, Phytolacca 15x, Pulsatilla 15x, Rhus tox. 15x, Ruta 15x, Sarcocollinum ac. 15x, Sticta 15x, Stramonium 15x.

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

Stock# **N019** Lot#

**ACHES - PAINS**

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

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55714-2383
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ACONITUM NAPELLUS</b> (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	15 [hp_X] in 1 g
<b>SILVER NITRATE</b> (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A)	SILVER NITRATE	15 [hp_X] in 1 g
<b>ARNICA MONTANA</b> (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	15 [hp_X] in 1 g
<b>BRYONIA ALBA ROOT</b> (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	15 [hp_X] in 1 g
<b>COLCHICUM AUTUMNALE BULB</b> (UNII: 993QHL78E6) (COLCHICUM AUTUMNALE BULB - UNII:993QHL78E6)	COLCHICUM AUTUMNALE BULB	15 [hp_X] in 1 g
<b>GUAIAC</b> (UNII: 03C8A0DFJ8) (GUAIAC - UNII:03C8A0DFJ8)	GUAIAC	15 [hp_X] in 1 g

<b>HYPERICUM PERFORATUM</b> (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	15 [hp_X] in 1 g
<b>KALMIA LATIFOLIA LEAF</b> (UNII: 79N6542N18) (KALMIA LATIFOLIA LEAF - UNII:79N6542N18)	KALMIA LATIFOLIA LEAF	15 [hp_X] in 1 g
<b>PHOSPHORUS</b> (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	15 [hp_X] in 1 g
<b>PHYTOLACCA AMERICANA ROOT</b> (UNII: 11E6V18VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6V18VEG)	PHYTOLACCA AMERICANA ROOT	15 [hp_X] in 1 g
<b>PULSATILLA VULGARIS</b> (UNII: I76KB35JEV) (PULSATILLA VULGARIS - UNII:I76KB35JEV)	PULSATILLA VULGARIS	15 [hp_X] in 1 g
<b>TOXICODENDRON PUBESCENS LEAF</b> (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	15 [hp_X] in 1 g
<b>RUTA GRAVEOLENS FLOWERING TOP</b> (UNII: N94C2U587S) (RUTA GRAVEOLENS FLOWERING TOP - UNII:N94C2U587S)	RUTA GRAVEOLENS FLOWERING TOP	15 [hp_X] in 1 g
<b>LACTIC ACID, L-</b> (UNII: F9S9FFU82N) (LACTIC ACID, L- - UNII:F9S9FFU82N)	LACTIC ACID, L-	15 [hp_X] in 1 g
<b>LOBARIA PULMONARIA</b> (UNII: D1YM0P5Z2T) (LOBARIA PULMONARIA - UNII:D1YM0P5Z2T)	LOBARIA PULMONARIA	15 [hp_X] in 1 g
<b>DATURA STRAMONIUM</b> (UNII: G6W4F0V8Z3) (DATURA STRAMONIUM - UNII:G6W4F0V8Z3)	DATURA STRAMONIUM	15 [hp_X] in 1 g
<b>HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK</b> (UNII: T7S323PKJS) (HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK	6 [hp_X] in 1 g
<b>TARAXACUM OFFICINALE</b> (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)	TARAXACUM OFFICINALE	6 [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:55714-2383-1	28 g in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/26/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/26/2018	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-2383)

