

ACHES - PAINS- 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.

Aches - Pains 2382L

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.

DOSAGE & ADMINISTRATION SECTION

Directions: Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) as needed or as directed by a health professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

OTC - PREGNANCY OR BREAST FEEDING SECTION

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

OTC - QUESTIONS SECTION

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

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

INACTIVE INGREDIENT SECTION

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

OTC - PURPOSE SECTION

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.

INDICATIONS & USAGE SECTION

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

PACKAGE LABEL

newtonlabs.net ~ Questions? 800.448.7256
 Newton Laboratories, Inc. FDA Est# 1051203 • Conway, 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#
 55714-2382-1

**Aches
 ~Pains**

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

1 FL OZ (30 ML)

Directions: Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) as needed or as directed by a health professional. Sensitive persons begin with 1 drop 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, Sarcolacticum ac. 15x, Sticta 15x, Stramonium 15x.

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

Stock# **N019** Lot#

ACHES - PAINS

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2382
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
GUAIAIC (UNII: 03C8A0DFJ8) (GUAIAIC - UNII:03C8A0DFJ8)	GUAIAIC	15 [hp_X] in 1 mL

HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	15 [hp_X] in 1 mL
KALMIA LATIFOLIA LEAF (UNII: 79N6542N18) (KALMIA LATIFOLIA LEAF - UNII:79N6542N18)	KALMIA LATIFOLIA LEAF	15 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	15 [hp_X] in 1 mL
PHYTOLACCA AMERICANA ROOT (UNII: 11E6V18VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6V18VEG)	PHYTOLACCA AMERICANA ROOT	15 [hp_X] in 1 mL
PULSATILLA VULGARIS (UNII: I76KB35JEV) (PULSATILLA VULGARIS - UNII:I76KB35JEV)	PULSATILLA VULGARIS	15 [hp_X] in 1 mL
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	15 [hp_X] in 1 mL
RUTA GRAVEOLENS FLOWERING TOP (UNII: N94C2U587S) (RUTA GRAVEOLENS FLOWERING TOP - UNII:N94C2U587S)	RUTA GRAVEOLENS FLOWERING TOP	15 [hp_X] in 1 mL
LACTIC ACID, L- (UNII: F9S9FFU82N) (LACTIC ACID, L- - UNII:F9S9FFU82N)	LACTIC ACID, L-	15 [hp_X] in 1 mL
LOBARIA PULMONARIA (UNII: D1YM0P5Z2T) (LOBARIA PULMONARIA - UNII:D1YM0P5Z2T)	LOBARIA PULMONARIA	15 [hp_X] in 1 mL
DATURA STRAMONIUM (UNII: G6W4F0V8Z3) (DATURA STRAMONIUM - UNII:G6W4F0V8Z3)	DATURA STRAMONIUM	15 [hp_X] in 1 mL
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS) (HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK	6 [hp_X] in 1 mL
TARAXACUM OFFICINALE (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)	TARAXACUM OFFICINALE	6 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2382-0	0.5 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/26/2018	08/01/2019
2	NDC:55714-2382-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/26/2018	
3	NDC:55714-2382-2	50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/26/2018	08/01/2019

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(55714-2382)

Revised: 11/2020

Newton Laboratories, Inc.