

**BREAST CARE - FIBROCYSTIC- bufo rana, apis mel., asterias rubens, belladonna, bryonia, calc. carb., chamomilla, chimaphila umbellata, cinchona, conium, croton, echinacea, graphites, helonias dioica, lachesis, merc. viv., phellandrium aquaticum phosphorus, phytolacca, pulsatilla, sanguinaria, silicea, hamamelis, ruta, 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.*

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**Breast 4828L**

## **INDICATIONS & USAGE SECTION**

Formulated for associated symptoms such as breast tenderness, nursing discomfort and pre-menstrual swelling.

## **DOSAGE & ADMINISTRATION SECTION**

**Directions:** Ages 12 and up take 6 drops by mouth one to four times daily or as directed by a health professional.

## **OTC - ACTIVE INGREDIENT SECTION**

Equal parts of Hamamelis 6x, Phytolacca 6x, Ruta 6x, Taraxacum 6x, Apis mel. 15x, Asterias 15x, Belladonna 15x, Bryonia 15x, Bufo 15x, Calc. carb. 15x, Chamomilla 15x, Chimaphila umb. 15x, Cinchona 15x, Conium 15x, Croton 15x, Echinacea 15x, Graphites 15x, Helonias 15x, Lachesis 15x, Merc. viv. 15x, Phellandrium 15x, Phos. 15x, Phytolacca 15x, Pulsatilla 15x, Sanguinaria 15x, Silicea 15x.

## **OTC - PURPOSE SECTION**

## **INACTIVE INGREDIENT SECTION**

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

## **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**

**Keep out of reach of children.**

**PACKAGE LABEL**

**newtonlabs.net ~ Questions? 800.448.7256**  
 Newton Laboratories, Inc. FDA Est# 1051203 • Conyers, GA 30013

**NEWTON homeopathics™ PRO**

NDC# 55714-4828-1

**Breast Care ~ Fibrocystic**

Formulated for associated symptoms such as breast tenderness, nursing discomfort and pre-menstrual swelling.

**1 FL OZ (30 ML)**

Dispensed by health professionals - not sold over-the-counter.  
**Directions:** Ages 12 and up, take 6 drops by mouth one to four times daily or as directed by a health professional.  
**Active Ingredients:** Equal parts of Hamamelis 6x, Phytolacca 6x, Ruta 6x, Taraxacum 6x, Apis mel. 15x, Asterias 15x, Belladonna 15x, Bryonia 15x, Bufo 15x, Calc. carb. 15x, Chamomilla 15x, Chimaphila umb. 15x, Cinchona 15x, Conium 15x, Croton 15x, Echinacea 15x, Graphites 15x, Helonias 15x, Lachesis 15x, Merc. viv. 15x, Phellandrium 15x, Phos. 15x, Phytolacca 15x, Pulsatilla 15x, Sanguinaria 15x, Silicea 15x.  
**Inactive Ingredients:** USP Purified water; USP Gluten-free, non-GMO, organic cane alcohol 20%.

Stock# R054 Lot#

**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.**

**BREAST CARE - FIBROCYSTIC**

bufo rana, apis mel., asterias rubens, belladonna, bryonia, calc. carb., chamomilla, chimaphila umbellata, cinchona, conium, croton, echinacea, graphites, helonias dioica, lachesis, merc. viv., phellandrium aquaticum phosphorus, phytolacca, pulsatilla, sanguinaria, silicea, hamamelis, ruta, taraxacum liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55714-4828
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BUFO BUFO CUTANEOUS GLAND</b> (UNII: Q59QU6N72Q) (BUFO BUFO CUTANEOUS GLAND - UNII:Q59QU6N72Q)	BUFO BUFO CUTANEOUS GLAND	15 [hp_X] in 1 mL
<b>APIS MELLIFERA</b> (UNII: 7S82P3R43Z) (APIS MELLIFERA - UNII:7S82P3R43Z)	APIS MELLIFERA	15 [hp_X] in 1 mL
<b>ASTERIAS RUBENS</b> (UNII: A7FYY9Q742) (ASTERIAS RUBENS - UNII:A7FYY9Q742)	ASTERIAS RUBENS	15 [hp_X] in 1 mL
<b>ATROPA BELLADONNA</b> (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	15 [hp_X] in 1 mL
<b>BRYONIA ALBA ROOT</b> (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	15 [hp_X] in 1 mL
<b>OYSTER SHELL CALCIUM CARBONATE, CRUDE</b> (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	15 [hp_X] in 1 mL

<b>MATRICARIA CHAMOMILLA</b> (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	15 [hp_X] in 1 mL
<b>CHIMAPHILA UMBELLATA</b> (UNII: WCK21A9W9J) (CHIMAPHILA UMBELLATA - UNII:WCK21A9W9J)	CHIMAPHILA UMBELLATA	15 [hp_X] in 1 mL
<b>CINCHONA OFFICINALIS BARK</b> (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB)	CINCHONA OFFICINALIS BARK	15 [hp_X] in 1 mL
<b>CONIUM MACULATUM FLOWERING TOP</b> (UNII: Q28R5GF371) (CONIUM MACULATUM FLOWERING TOP - UNII:Q28R5GF371)	CONIUM MACULATUM FLOWERING TOP	15 [hp_X] in 1 mL
<b>CROTON TIGLIUM SEED</b> (UNII: 0HK2GZK66E) (CROTON TIGLIUM SEED - UNII:0HK2GZK66E)	CROTON TIGLIUM SEED	15 [hp_X] in 1 mL
<b>ECHINACEA, UNSPECIFIED</b> (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	15 [hp_X] in 1 mL
<b>GRAPHITE</b> (UNII: 4QQN74LH4O) (GRAPHITE - UNII:4QQN74LH4O)	GRAPHITE	15 [hp_X] in 1 mL
<b>CHAMAELIRIUM LUTEUM ROOT</b> (UNII: DQV54Y5H3U) (CHAMAELIRIUM LUTEUM ROOT - UNII:DQV54Y5H3U)	CHAMAELIRIUM LUTEUM ROOT	15 [hp_X] in 1 mL
<b>LACHESIS MUTA VENOM</b> (UNII: VSW71SS07I) (LACHESIS MUTA VENOM - UNII:VSW71SS07I)	LACHESIS MUTA VENOM	15 [hp_X] in 1 mL
<b>MERCURY</b> (UNII: FXS1BY2PGL) (MERCURY - UNII:FXS1BY2PGL)	MERCURY	15 [hp_X] in 1 mL
<b>OENANTHE AQUATICA FRUIT</b> (UNII: N4LEE4Z93J) (OENANTHE AQUATICA FRUIT - UNII:N4LEE4Z93J)	OENANTHE AQUATICA FRUIT	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: 11E6V18VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6V18VEG)	PHYTOLACCA AMERICANA ROOT	15 [hp_X] in 1 mL
<b>ANEMONE PULSATILLA</b> (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	15 [hp_X] in 1 mL
<b>SANGUINARIA CANADENSIS ROOT</b> (UNII: N9288CD508) (SANGUINARIA CANADENSIS ROOT - UNII:N9288CD508)	SANGUINARIA CANADENSIS ROOT	15 [hp_X] in 1 mL
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	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	6 [hp_X] in 1 mL
<b>RUTA GRAVEOLENS FLOWERING TOP</b> (UNII: N94C2U587S) (RUTA GRAVEOLENS FLOWERING TOP - UNII:N94C2U587S)	RUTA GRAVEOLENS FLOWERING TOP	6 [hp_X] in 1 mL
<b>TARAXACUM OFFICINALE</b> (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)	TARAXACUM OFFICINALE	6 [hp_X] in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-4828-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/02/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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unapproved homeopathic	09/02/2018
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**Labeler** - Newton Laboratories, Inc. (788793610)

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-4828)

Revised: 12/2020

Newton Laboratories, Inc.