

**ORAL CARE-GINGIVITIS- aconitum nap., arnica, arsenicum alb., baptisia, belladonna, bryonia, calendula, chamomilla, chelidonium majus, crotalus horridus, gelsemium, hepar sulph. calc., kreosotum, merc. viv., myrrha, nux vom., phosphorus, phytolacca, plantago, rhus toxicodendron, silicea, staphysag., echinacea 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.*

-----  
**Oral 4789L**

## **INDICATIONS & USAGE SECTION**

Formulated for symptoms associated with periodontal conditions such as gingivitis, halitosis, teeth pain and gum sensitivity.

## **DOSAGE & ADMINISTRATION SECTION**

**Directions:** Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) one to four times daily or as directed by a health professional.

## **OTC - ACTIVE INGREDIENT SECTION**

Equal parts of Chamomilla 6x, Echinacea 6x, Aconitum nap. 15x, Arnica 15x, Arsenicum alb. 15x, Baptisia 15x, Belladonna 15x, Bryonia 15x, Calendula 15x, Chamomilla 15x, Chelidonium majus 15x, Crotalus horridus 15x, Gelsemium 15x, Hepar sulph. calc. 15x, Kreosotum 15x, Merc. viv. 15x, Myrrha 15x, Nux vom. 15x, Phosphorus 15x, Phytolacca 15x, Plantago 15x, Rhus toxicodendron 15x, Silicea 15x, Staphysag. 15x.

## **OTC - PURPOSE SECTION**

Formulated for symptoms associated peridontal conditions such as gingivitis, halitosis, teeth pain and gum sensitivity.

## **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**

**ORAL CARE-GINGIVITIS**

aconitum nap., arnica, arsenicum alb., baptisia, belladonna, bryonia, calendula, chamomilla, chelidonium majus, crotalus horridus, gelsemium, hepar sulph. calc., kreosotum, merc. viv., myrrha, nux vom., phosphorus, phytolacca, plantago, rhus toxicodendron, silicea, staphysag., echinacea liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55714-4789
<b>Route of Administration</b>	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
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	15 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	15 [hp_X] in 1 mL
BAPTISIA TINCTORIA ROOT (UNII: 5EF0HWI5WU) (BAPTISIA TINCTORIA ROOT - UNII:5EF0HWI5WU)	BAPTISIA TINCTORIA ROOT	15 [hp_X] in 1 mL
ATROPA BELLADONNA (UNII: WQZGCP9E9D) (ATROPA BELLADONNA		15 [hp_X]

<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>CALENDULA OFFICINALIS FLOWERING TOP</b> (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	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>CHELIDONIUM MAJUS</b> (UNII: 7E889U5RNN) (CHELIDONIUM MAJUS - UNII:7E889U5RNN)	CHELIDONIUM MAJUS	15 [hp_X] in 1 mL
<b>CROTALUS HORRIDUS HORRIDUS VENOM</b> (UNII: YHA2XLJ956) (CROTALUS HORRIDUS HORRIDUS VENOM - UNII:YHA2XLJ956)	CROTALUS HORRIDUS HORRIDUS VENOM	15 [hp_X] in 1 mL
<b>GELSEMIUM SEMPERVIRENS ROOT</b> (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	15 [hp_X] in 1 mL
<b>CALCIUM SULFIDE</b> (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	15 [hp_X] in 1 mL
<b>WOOD CREOSOTE</b> (UNII: 3JYG22FD73) (WOOD CREOSOTE - UNII:3JYG22FD73)	WOOD CREOSOTE	15 [hp_X] in 1 mL
<b>MERCURY</b> (UNII: FXS1BY2PGL) (MERCURY - UNII:FXS1BY2PGL)	MERCURY	15 [hp_X] in 1 mL
<b>MYRRH</b> (UNII: JC71GJ1F3L) (MYRRH - UNII:JC71GJ1F3L)	MYRRH	15 [hp_X] in 1 mL
<b>STRYCHNOS NUX-VOMICA SEED</b> (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	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>PLANTAGO MAJOR</b> (UNII: W2469WNO6U) (PLANTAGO MAJOR - UNII:W2469WNO6U)	PLANTAGO MAJOR	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>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	15 [hp_X] in 1 mL
<b>DELPHINIUM STAPHISAGRIA SEED</b> (UNII: 00543AP1JV) (DELPHINIUM STAPHISAGRIA SEED - UNII:00543AP1JV)	DELPHINIUM STAPHISAGRIA SEED	15 [hp_X] in 1 mL
<b>ECHINACEA, UNSPECIFIED</b> (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	6 [hp_X] in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-4789-1	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
--------------------	--	----------------------	--------------------

unapproved homeopathic

09/02/2019

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

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-4789)

Revised: 12/2020

Newton Laboratories, Inc.