

**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, slicea, 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 Care - Gingivitis

INDICATIONS & USAGE SECTION

Oral Care - Gingivitis Formulated for symptoms associated with periodontal conditions such as mouth ulcerations, gingivitis, halitosis, teeth pain and gum sensitivity.

DOSAGE & ADMINISTRATION SECTION

Directions: ORAL USE ONLY - SHAKE WELL. Ages 12 and up, take 6 drops orally (ages 0 to 11, give 3 drops) one to four times daily or as directed by a healthcare professional.

ACTIVE INGREDIENT SECTION

Aconitum nap. 20x, Arnica 20x, Arsenicum alb. 20x, Baptisia 20x, Belladonna 20x, Bryonia 20x, Calendula 20x, Chamomilla 20x, Chelidonium majus 20x, Crotalus horridus 20x, Gelsemium 20x, Hepar sulph. calc. 20x, Kreosotum 20x, Merc. viv. 20x, Myrrha 20x, Nux vom. 20x, Phosphorus 20x, Phytolacca 20x, Plantago 20x, Rhus toxicodendron 20x, Silicea 20x, Staphysag. 20x, Chamomilla 8x, Echinacea 8x, Chamomilla 3x, Echinacea 3x.

PURPOSE SECTION

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

INACTIVE INGREDIENT SECTION

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

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.

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

KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children

PACKAGE LABEL.

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Questions? 1.800.448.7256
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NDC# 55714-4440-1

Oral Care~ Gingivitis

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

1 fl oz (29.57 ml)

Dispensed by healthcare professionals only.
 Not for over-the-counter sale.
Directions: ORAL USE ONLY - SHAKE WELL.
 Ages 12 and up, take 6 drops orally (ages 0 to 11, give 3 drops) one to four times daily or as directed by a healthcare professional.
Active Ingredients: Aconitum nap. 20x, Arnica 20x, Arsenicum alb. 20x, Baptisia 20x, Belladonna 20x, Bryonia 20x, Calendula 20x, Chamomilla 20x, Chelidonium majus 20x, Crotalus horridus 20x, Gelsemium 20x, Hepar sulph. calc. 20x, Kreosotum 20x, Merc. viv. 20x, Myrrha 20x, Nux vom. 20x, Phosphorus 20x, Phytolacca 20x, Plantago 20x, Rhus toxicodendron 20x, Silicea 20x, Staphysag. 20x, Chamomilla 8x, Echinacea 8x, Chamomilla 3x, Echinacea 3x.
Inactive Ingredients: USP Purified water; USP Gluten-free, non-GMO, organic cane dispensing alcohol 20%.

Stock# **R021** Lot#

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, slicea, staphysag., echinacea liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:55714-4440
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Aconitum Napellus (UNII: U0NQ8555JD) (Aconitum Napellus - UNII:U0NQ8555JD)	Aconitum Napellus	20 [hp_X] in 1 mL
Arnica Montana (UNII: O80TY208ZW) (Arnica Montana - UNII:O80TY208ZW)	Arnica Montana	20 [hp_X] in 1 mL
Arsenic Trioxide (UNII: S7V92P67HO) (Arsenic Cation (3+) - UNII:C96613F5AV)	Arsenic Trioxide	20 [hp_X] in 1 mL
Baptisia Tinctoria Root (UNII: 5EF0HWI5WU) (Baptisia Tinctoria Root -	Baptisia Tinctoria Root	20 [hp_X]

UNII:5EF0HWI5WU)	Dapsula tricolor root	in 1 mL
Atropa Belladonna (UNII: WQZ3G9PF0H) (Atropa Belladonna - UNII:WQZ3G9PF0H)	Atropa Belladonna	20 [hp_X] in 1 mL
Bryonia Alba Root (UNII: T7J046YI2B) (Bryonia Alba Root - UNII:T7J046YI2B)	Bryonia Alba Root	20 [hp_X] in 1 mL
Calendula Officinalis Flowering Top (UNII: 18E7415PXQ) (Calendula Officinalis Flowering Top - UNII:18E7415PXQ)	Calendula Officinalis Flowering Top	20 [hp_X] in 1 mL
Matricaria Recutita (UNII: G0R4UBI2ZZ) (Matricaria Recutita - UNII:G0R4UBI2ZZ)	Matricaria Recutita	20 [hp_X] in 1 mL
Chelidonium Majus (UNII: 7E889U5RNN) (Chelidonium Majus - UNII:7E889U5RNN)	Chelidonium Majus	20 [hp_X] in 1 mL
Crotalus Horridus Horridus Venom (UNII: YHA2XLJ956) (Crotalus Horridus Horridus Venom - UNII:YHA2XLJ956)	Crotalus Horridus Horridus Venom	20 [hp_X] in 1 mL
Gelsemium Sempervirens Root (UNII: 639KR60Q1Q) (Gelsemium Sempervirens Root - UNII:639KR60Q1Q)	Gelsemium Sempervirens Root	20 [hp_X] in 1 mL
Calcium Sulfide (UNII: 1MBW07J51Q) (Calcium Sulfide - UNII:1MBW07J51Q)	Calcium Sulfide	20 [hp_X] in 1 mL
Wood Creosote (UNII: 3JYG22FD73) (Wood Creosote - UNII:3JYG22FD73)	Wood Creosote	20 [hp_X] in 1 mL
Mercury (UNII: FXS1BY2PGL) (Mercury - UNII:FXS1BY2PGL)	Mercury	20 [hp_X] in 1 mL
Myrrh (UNII: JC71GJ1F3L) (Myrrh - UNII:JC71GJ1F3L)	Myrrh	20 [hp_X] in 1 mL
Strychnos Nux-vomica Seed (UNII: 269XH13919) (Strychnos Nux-vomica Seed - UNII:269XH13919)	Strychnos Nux-vomica Seed	20 [hp_X] in 1 mL
Phosphorus (UNII: 27YLU75U4W) (Phosphorus - UNII:27YLU75U4W)	Phosphorus	20 [hp_X] in 1 mL
Plantago Major (UNII: W2469WNO6U) (Plantago Major - UNII:W2469WNO6U)	Plantago Major	20 [hp_X] in 1 mL
Toxicodendron Pubescens Leaf (UNII: 6IO182RP7A) (Toxicodendron Pubescens Leaf - UNII:6IO182RP7A)	Toxicodendron Pubescens Leaf	20 [hp_X] in 1 mL
Silicon Dioxide (UNII: ETJ7Z6XBU4) (Silicon Dioxide - UNII:ETJ7Z6XBU4)	Silicon Dioxide	20 [hp_X] in 1 mL
Delphinium Staphisagria Seed (UNII: 00543AP1JV) (Delphinium Staphisagria Seed - UNII:00543AP1JV)	Delphinium Staphisagria Seed	20 [hp_X] in 1 mL
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	8 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Alcohol (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-4440-1	29.57 mL in 1 BOTTLE, GLASS		
2	NDC:55714-4440-2	59.14 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		06/01/2011	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-4440)

Revised: 6/2011

Newton Laboratories, Inc.