

**TEETH - GUMS - 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 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.

Teeth - Gums

INDICATIONS & USAGE SECTION

Teeth - Gums Formulated for associated symptoms including mouth sores, bad breath, toothache, inflammation and gum sensitivity.

DOSAGE & ADMINISTRATION SECTION

Directions: Ages 12 and up, take 6 pellets orally (ages 0 to 11, give 3 pellets) one to four times daily or as directed by a healthcare professional. Under age 2, crush or dissolve pellets in purified water. Sensitive persons begin with 1 pellet and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

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, Chamomilla 3x, Echinacea 3x.

OTC - PURPOSE SECTION

Formulated for associated symptoms including mouth sores, bad breath, toothache, inflammation and gum sensitivity.

INACTIVE INGREDIENT SECTION

Inactive Ingredients: Gluten-free, non-GMO, beet-derived sucrose pellets.

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.

OTC - 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.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

PACKAGE LABEL

www.newtonlabs.net
 Newton Laboratories, Inc. FDA Est#1051203 • Conyers, GA 30012
Questions? 1.800.448.7256
Warnings: 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.



NDC#
55714-2283-1

Teeth ~Gums

Formulated for associated symptoms including mouth sores, bad breath, toothache, inflammation and gum sensitivity.

1 oz (28.35 g)

Directions: Ages 12 and up, take 6 pellets orally (ages 0 to 11, give 3 pellets) one to four times daily or as directed by a healthcare professional. Under age 2, crush or dissolve pellets in purified water. Sensitive persons begin with 1 pellet and gradually increase to full dose.

Active Ingredients: 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, Chamomilla 3x, Echinacea 3x.

Inactive Ingredients: Gluten-free, non-GMO, beet-derived sucrose pellets.

Stock# **N042** Lot#

TEETH - GUMS

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 pellet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2283
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 g
Arnica Montana (UNII: O80TY208ZW) (Arnica Montana - UNII:O80TY208ZW)	Arnica Montana	15 [hp_X] in 1 g
Arsenic Trioxide (UNII: S7V92P67HO) (Arsenic Cation (3+) - UNII:C96613F5AV)	Arsenic Trioxide	15 [hp_X] in 1 g

Baptisia Tinctoria (UNII: 5K1UO2888Y) (Baptisia Tinctoria - UNII:5K1UO2888Y)	Baptisia Tinctoria	15 [hp_X] in 1 g
Atropa Belladonna (UNII: WQZ3G9PF0H) (Atropa Belladonna - UNII:WQZ3G9PF0H)	Atropa Belladonna	15 [hp_X] in 1 g
Bryonia Alba Root (UNII: T7J046YI2B) (Bryonia Alba Root - UNII:T7J046YI2B)	Bryonia Alba Root	15 [hp_X] in 1 g
Calendula Officinalis Flowering Top (UNII: 18E7415PXQ) (Calendula Officinalis Flowering Top - UNII:18E7415PXQ)	Calendula Officinalis Flowering Top	15 [hp_X] in 1 g
Matricaria Recutita (UNII: G0R4UBI2ZZ) (Matricaria Recutita - UNII:G0R4UBI2ZZ)	Matricaria Recutita	15 [hp_X] in 1 g
Chelidonium Majus (UNII: 7E889U5RNN) (Chelidonium Majus - UNII:7E889U5RNN)	Chelidonium Majus	15 [hp_X] in 1 g
Crotalus Horridus Horridus Venom (UNII: YHA2XLJ956) (Crotalus Horridus Horridus Venom - UNII:YHA2XLJ956)	Crotalus Horridus Horridus Venom	15 [hp_X] in 1 g
Gelsemium Sempervirens Root (UNII: 639KR60Q1Q) (Gelsemium Sempervirens Root - UNII:639KR60Q1Q)	Gelsemium Sempervirens Root	15 [hp_X] in 1 g
Calcium Sulfide (UNII: 1MBW07J51Q) (Calcium Sulfide - UNII:1MBW07J51Q)	Calcium Sulfide	15 [hp_X] in 1 g
Wood Creosote (UNII: 3JYG22FD73) (Wood Creosote - UNII:3JYG22FD73)	Wood Creosote	15 [hp_X] in 1 g
Mercury (UNII: FXS1BY2PGL) (Mercury - UNII:FXS1BY2PGL)	Mercury	15 [hp_X] in 1 g
Myrrh (UNII: JC71GJ1F3L) (Myrrh - UNII:JC71GJ1F3L)	Myrrh	15 [hp_X] in 1 g
Strychnos Nux-vomica Seed (UNII: 269XH13919) (Strychnos Nux-vomica Seed - UNII:269XH13919)	Strychnos Nux-vomica Seed	15 [hp_X] in 1 g
Phosphorus (UNII: 27YLU75U4W) (Phosphorus - UNII:27YLU75U4W)	Phosphorus	15 [hp_X] in 1 g
Phytolacca Americana Root (UNII: 11E6VI8VEG) (Phytolacca Americana Root - UNII:11E6VI8VEG)	Phytolacca Americana Root	15 [hp_X] in 1 g
Plantago Major (UNII: W2469WNO6U) (Plantago Major - UNII:W2469WNO6U)	Plantago Major	15 [hp_X] in 1 g
Toxicodendron Pubescens Leaf (UNII: 6IO182RP7A) (Toxicodendron Pubescens Leaf - UNII:6IO182RP7A)	Toxicodendron Pubescens Leaf	15 [hp_X] in 1 g
Silicon Dioxide (UNII: ETJ7Z6XBU4) (Silicon Dioxide - UNII:ETJ7Z6XBU4)	Silicon Dioxide	15 [hp_X] in 1 g
Delphinium Staphisagria Seed (UNII: 00543APIJV) (Delphinium Staphisagria Seed - UNII:00543APIJV)	Delphinium Staphisagria Seed	15 [hp_X] in 1 g
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	3 [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:55714-2283-1	28.35 g in 1 BOTTLE, GLASS		
2	NDC:55714-2283-2	56.7 g in 1 BOTTLE, GLASS		
3	NDC:55714-2283-0	7.08 g in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/01/2011	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-2283)

Revised: 3/2011

Newton Laboratories, Inc.