

**HEMORRHOIDS - elaps corallinus, aesculus hipp., aloe, arsenicum alb., bryonia, calc. fluor., capsicum, collinsonia, crotalus horridus, hamamelis, hydrofluoricum acidum, hypericum, lachesis, lycopodium, millefolium, naja, nux vom., paeonia, plantago, quercus glandium spiritus, ratanhia, vipera berus, echinacea, solidago, urtica ur. 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.

Hemorrhoids

INDICATIONS & USAGE SECTION

Hemorrhoids Formulated for symptoms associated with hemorrhoids such as difficult elimination, itching, inflammation, burning pain and pressure.

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. Sensitive persons begin with 1 drop and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Elaps corallinus 30x, Aesculus hipp.15x, Aloe 15x, Arsenicum alb. 15x, Bryonia 15x, Calc. fluor. 15x, Capsicum 15x, Collinsonia 15x, Crotalus horridus 15x, Hamamelis 15x, Hydrofluoricum acidum 15x, Hypericum 15x, Lachesis 15x, Lycopodium 15x, Millefolium 15x, Naja 15x, Nux vom. 15x, Paeonia 15x, Plantago 15x, Quercus glandium spiritus 15x, Ratanhia 15x, Vipera berus 15x, Aesculus hipp. 3x, Echinacea 3x, Solidago 3x, Urtica ur. 3x.

OTC - PURPOSE SECTION

Formulated for symptoms associated with hemorrhoids such as difficult elimination, itching, inflammation, burning pain and pressure.

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

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.

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 Newton Laboratories, Inc. FDA Est# 1051203 • Conway, GA 30012
Questions? 1.800.448.7256
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.



NDC#
55714-2220-1

Hemorrhoids

Formulated for symptoms associated with hemorrhoids such as difficult elimination, itching, inflammation, burning pain and pressure.

1 fl oz (29.57 ml)

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. Sensitive persons begin with 1 drop and gradually increase to full dose.
Active Ingredients: Elaps corallinus 30x, Aesculus hipp. 15x, Aloe 15x, Arsenicum alb. 15x, Bryonia 15x, Calc. fluor. 15x, Capsicum 15x, Collinsonia 15x, Crotaulus horridus 15x, Hamamelis 15x, Hydrofluoricum acidum 15x, Hypericum 15x, Lachesis 15x, Lycopodium 15x, Millefolium 15x, Naja 15x, Nux vom. 15x, Paeonia 15x, Plantago 15x, Quercus glandium spiritus 15x, Ratanhia 15x, Vipera berus 15x, Aesculus hipp. 3x, Echinacea 3x, Solidago 3x, Urtica ur. 3x.
Inactive Ingredients: USP Purified water; USP Gluten-free, non-GMO, organic cane dispensing alcohol 20%.

Stock# **N011** Lot#

HEMORRHOIDS

elaps corallinus, aesculus hipp., aloe, arsenicum alb., bryonia, calc. fluor., capsicum, collinsonia, crotaulus horridus, hamamelis, hydrofluoricum acidum, hypericum, lachesis, lycopodium, millefolium, naja, nux vom., paeonia, plantago, quercus glandium spiritus, ratanhia, vipera berus, echinacea, solidago, urtica ur. liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2220
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Micurus Corallinus Venom (UNII: V0S6H36980) (Micurus Corallinus Venom - UNII:V0S6H36980)	Micurus Corallinus Venom	30 [hp_X] in 1 mL
Horse Chestnut (UNII: 3C18L6RJAZ) (Horse Chestnut - UNII:3C18L6RJAZ)	Horse Chestnut	15 [hp_X] in 1 mL
Aloe (UNII: V5VD430YW9) (Aloe - UNII:V5VD430YW9)	Aloe	15 [hp_X] in 1 mL
Arsenic Trioxide (UNII: S7V92P67HO) (Arsenic Cation (3+) - UNII:C96613F5AV)	Arsenic Trioxide	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

Calcium Fluoride (UNII: O3B55K4YKI) (Fluoride Ion - UNII:Q80VPU408O)	Calcium Fluoride	15 [hp_X] in 1 mL
Capsicum (UNII: 00UK7646FG) (Capsicum - UNII:00UK7646FG)	Capsicum	15 [hp_X] in 1 mL
Collinsonia Canadensis Root (UNII: O2630F3XDR) (Collinsonia Canadensis Root - UNII:O2630F3XDR)	Collinsonia Canadensis Root	15 [hp_X] in 1 mL
Crotalus Horridus Horridus Venom (UNII: YHA2XLJ956) (Crotalus Horridus Horridus Venom - UNII:YHA2XLJ956)	Crotalus Horridus Horridus Venom	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	15 [hp_X] in 1 mL
Hydrofluoric Acid (UNII: RGL5YE86CZ) (Hydrofluoric Acid - UNII:RGL5YE86CZ)	Hydrofluoric Acid	15 [hp_X] in 1 mL
Hypericum Perforatum (UNII: XK4IUX8MNB) (Hypericum Perforatum - UNII:XK4IUX8MNB)	Hypericum Perforatum	15 [hp_X] in 1 mL
Lachesis Muta Venom (UNII: VSW71SS07I) (Lachesis Muta Venom - UNII:VSW71SS07I)	Lachesis Muta Venom	15 [hp_X] in 1 mL
Lycopodium Clavatum Spore (UNII: C88X29Y479) (Lycopodium Clavatum Spore - UNII:C88X29Y479)	Lycopodium Clavatum Spore	15 [hp_X] in 1 mL
Achillea Millefolium (UNII: 2FXJ6SW4PK) (Achillea Millefolium - UNII:2FXJ6SW4PK)	Achillea Millefolium	15 [hp_X] in 1 mL
Naja Naja Venom (UNII: ZZ4AG7L7VM) (Naja Naja Venom - UNII:ZZ4AG7L7VM)	Naja Naja Venom	15 [hp_X] in 1 mL
Strychnos Nux-vomica Seed (UNII: 269XH13919) (Strychnos Nux-vomica Seed - UNII:269XH13919)	Strychnos Nux-vomica Seed	15 [hp_X] in 1 mL
Paeonia Officinalis Root (UNII: 8R564U2E1P) (Paeonia Officinalis Root - UNII:8R564U2E1P)	Paeonia Officinalis Root	15 [hp_X] in 1 mL
Plantago Major (UNII: W2469WNO6U) (Plantago Major - UNII:W2469WNO6U)	Plantago Major	15 [hp_X] in 1 mL
Quercus Robur Nut (UNII: Q7MU1F4GLY) (Quercus Robur Nut - UNII:Q7MU1F4GLY)	Quercus Robur Nut	15 [hp_X] in 1 mL
Krameria Lappacea Root (UNII: P29ZH1A35Z) (Krameria Lappacea Root - UNII:P29ZH1A35Z)	Krameria Lappacea Root	15 [hp_X] in 1 mL
Vipera Berus Venom (UNII: 0ORO6NCA4M) (Vipera Berus Venom - UNII:0ORO6NCA4M)	Vipera Berus Venom	15 [hp_X] in 1 mL
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	3 [hp_X] in 1 mL
Solidago Virgaurea Flowering Top (UNII: 5405K23S50) (Solidago Virgaurea Flowering Top - UNII:5405K23S50)	Solidago Virgaurea Flowering Top	3 [hp_X] in 1 mL
Urtica Urens (UNII: IHN2NQ5OF9) (Urtica Urens - UNII:IHN2NQ5OF9)	Urtica Urens	3 [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:55714-2220-1	29.57 mL in 1 BOTTLE, GLASS		
2	NDC:55714-2220-2	59.14 mL in 1 BOTTLE, GLASS		
3	NDC:55714-2220-0	.5 mL 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(55714-2220) , API MANUFACTURE(55714-2220)

Revised: 3/2011

Newton Laboratories, Inc.