

SNORE SOOTHE - histaminum hydrochloricum laccaninum, arsenicum alb., belladonna bryonia, camphora, cistus canadensis, drosera, hepar sulph.calc., hydrastis, ignatia, iodium, kali bic., kali iod., nux vom., phosphorus, pulsatilla, sabadilla, silicea, sticta, sulphur, teucriummarum, verbascum, 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.

Snore - Soothe

INDICATIONS & USAGE SECTION

Snore - Soothe Formulated for symptoms associated with irregular airflow during sleep such as congestion, constriction, gland swelling, tension and inflammation.

DOSAGE & ADMINISTRATION SECTION

ORAL USE ONLY - SHAKE WELL. Ages 12 and up, take 6 drops orally (ages 0 to 11, give 3 drops) one hour before bedtime, and then again at bedtime. Repeat as needed or as directed by a healthcare professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Histaminum hydrochloricum 15x, Lac caninum 15x, Arsenicum alb. 10x, Belladonna 10x, Bryonia 10x, Camphora 10x, Cistus canadensis 10x, Drosera 10x, Hepar sulph.calc. 10x, Hydrastis 10x, Ignatia 10x, Iodium 10x, Kali bic. 10x, Kali iod. 10x, Nux vom. 10x, Phosphorus 10x, Pulsatilla 10x, Sabadilla 10x, Silicea 10x, Sticta 10x, Sulphur 10x, Teucrium marum 10x, Verbascum 10x, Echinacea 3x.

OTC - PURPOSE SECTION

Formulated for symptoms associated with irregular airflow during sleep such as congestion, constriction, gland swelling, tension and inflammation.

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

NEWTON homeopathics
Nurturing Naturally Since 1987™

NDC#
55714-2306-1

Snore~Soothe

Formulated for symptoms associated with irregular airflow during sleep such as congestion, constriction, gland swelling, tension and inflammation.

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 hour before bedtime, and then again at bedtime. Repeat as needed or as directed by a healthcare professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

Active Ingredients: Histaminum hydrochloricum 15x, Laccaninum 15x, Arsenicum alb. 10x, Belladonna 10x, Bryonia 10x, Camphora 10x, Cistus canadensis 10x, Drosera 10x, Hepar sulph. calc. 10x, Hydrastis 10x, Ignatia 10x, Iodium 10x, Kali bic. 10x, Kali iod. 10x, Nux vom. 10x, Phosphorus 10x, Pulsatilla 10x, Sabadilla 10x, Silicea 10x, Sticta 10x, Sulphur 10x, Teucrium marum 10x, Verbascum 10x, Echinacea 3x.

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

Stock# N054 Lot#

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SNORE SOOTHE

histaminum hydrochloricum laccaninum, arsenicum alb., belladonna bryonia, camphora, cistus canadensis, drosera, hepar sulph. calc., hydrastis, ignatia, iodium, kali bic., kali iod., nux vom., phosphorus, pulsatilla, sabadilla, silicea, sticta, sulphur, teucriummarum, verbascum, echinacea. liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2306
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Histamine Dihydrochloride (UNII: 3POA0Q644U) (Histamine - UNII:820484N8I3)	Histamine Dihydrochloride	15 [hp_X] in 1 mL
Canis Lupus Familiaris Milk (UNII: G39P120JQT) (Canis Lupus Familiaris Milk - UNII:G39P120JQT)	Canis Lupus Familiaris Milk	15 [hp_X] in 1 mL
Arsenic Trioxide (UNII: S7V92P67HO) (Arsenic Cation (3+) - UNII:C96613F5AV)	Arsenic Trioxide	10 [hp_X] in 1 mL
Atropa Belladonna (UNII: WQZ3G9PF0H) (Atropa Belladonna - UNII:WQZ3G9PF0H)	Atropa Belladonna	10 [hp_X] in 1 mL
Bryonia Alba Root (UNII: T7J046YI2B) (Bryonia Alba Root - UNII:T7J046YI2B)	Bryonia Alba Root	10 [hp_X] in 1 mL
Campher (natural) (UNII: N20HF7Q941) (Campher (natural) - UNII:N20HF7Q941)	Campher (natural)	10 [hp_X]

Camphor (natural) (UNII: N201LE/Q541) (Camphor (natural) - UNII:N201LE/Q541)	Camphor (natural)	in 1 mL
Helianthemum Canadense (UNII: 46G3W789Q3) (Helianthemum Canadense - UNII:46G3W789Q3)	Helianthemum Canadense	10 [hp_X] in 1 mL
Drosera Rotundifolia Flowering Top (UNII: 75O014T1HG) (Drosera Rotundifolia Flowering Top - UNII:75O014T1HG)	Drosera Rotundifolia Flowering Top	10 [hp_X] in 1 mL
Calcium Sulfide (UNII: 1MBW07J51Q) (Calcium Sulfide - UNII:1MBW07J51Q)	Calcium Sulfide	10 [hp_X] in 1 mL
Goldenseal (UNII: ZW3Z11D0JV) (Goldenseal - UNII:ZW3Z11D0JV)	Goldenseal	10 [hp_X] in 1 mL
Strychnos Ignatii Seed (UNII: 1NM3M2487K) (Strychnos Ignatii Seed - UNII:1NM3M2487K)	Strychnos Ignatii Seed	10 [hp_X] in 1 mL
Iodine (UNII: 9679TC07X4) (Iodine - UNII:9679TC07X4)	Iodine	10 [hp_X] in 1 mL
Potassium Dichromate (UNII: T4423S18FM) (Dichromate Ion - UNII:9LKY4BFN2V)	Potassium Dichromate	10 [hp_X] in 1 mL
Potassium Iodide (UNII: 1C4QK22F9J) (Iodide Ion - UNII:09G4I6V86Q)	Potassium Iodide	10 [hp_X] in 1 mL
Strychnos Nux-vomica Seed (UNII: 269XH13919) (Strychnos Nux-vomica Seed - UNII:269XH13919)	Strychnos Nux-vomica Seed	10 [hp_X] in 1 mL
Phosphorus (UNII: 27YLU75U4W) (Phosphorus - UNII:27YLU75U4W)	Phosphorus	10 [hp_X] in 1 mL
Pulsatilla Vulgaris (UNII: I76KB35JEV) (Pulsatilla Vulgaris - UNII:I76KB35JEV)	Pulsatilla Vulgaris	10 [hp_X] in 1 mL
Schoenocaulon Officinale Seed (UNII: 6NAF1689IO) (Schoenocaulon Officinale Seed - UNII:6NAF1689IO)	Schoenocaulon Officinale Seed	10 [hp_X] in 1 mL
Silicon Dioxide (UNII: ETJ7Z6XBU4) (Silicon Dioxide - UNII:ETJ7Z6XBU4)	Silicon Dioxide	10 [hp_X] in 1 mL
Lobaria Pulmonaria (UNII: D1YM0P5Z2T) (Lobaria Pulmonaria - UNII:D1YM0P5Z2T)	Lobaria Pulmonaria	10 [hp_X] in 1 mL
Sulfur (UNII: 70FD1KFU70) (Sulfur - UNII:70FD1KFU70)	Sulfur	10 [hp_X] in 1 mL
Teucrium Marum (UNII: 10464S0TAA) (Teucrium Marum - UNII:10464S0TAA)	Teucrium Marum	10 [hp_X] in 1 mL
Verbascum Thapsus (UNII: C9TD27U172) (Verbascum Thapsus - UNII:C9TD27U172)	Verbascum Thapsus	10 [hp_X] in 1 mL
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	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:55714-2306-1	29.57 mL in 1 BOTTLE, GLASS		
2	NDC:55714-2306-2	59.14 mL in 1 BOTTLE, GLASS		
3	NDC:55714-2306-0	.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(55714-2306) , API MANUFACTURE(55714-2306)

Revised: 3/2011

Newton Laboratories, Inc.