

**INSOMNIA - absinthium, anacardium orientale, arg. nit., arsenicum alb., belladonna, bryonia, calc. carb., camphora, chamomilla, cimicifuga, cinchona, coffea cruda, cypripedium, gelsemium, humulus, hyoscyamus, ignatia, kali brom., nux vom., passiflora, pulsatilla, scutellaria lateriflora, sepia, thuja occ., valeriana 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.

Insomnia

INDICATIONS & USAGE SECTION

Insomnia Formulated for associated symptoms such as the inability to fall asleep as well as return to sleep after waking, frequent waking and restlessness.

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 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

Absinthium 10x, Anacardium orientale 10x, Arg. nit. 10x, Arsenicum alb. 10x, Belladonna 10x, Bryonia 10x, Calc. carb. 10x, Camphora 10x, Chamomilla 10x, Cimicifuga 10x, Cinchona 10x, Coffea cruda 10x, Cypripedium 10x, Gelsemium 10x, Humulus 10x, Hyoscyamus 10x, Ignatia 10x, Kali brom.10x, Nux vom. 10x, Passiflora 10x, Pulsatilla 10x, Scutellaria lateriflora 10x, Sepia 10x, Thuja occ. 10x, Passiflora 3x, Valeriana 3x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as the inability to fall asleep as well as return to sleep after waking, frequent waking and restlessness.

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

www.newton1labs.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.

NEWTON
homeopathics 
Nurturing Naturally Since 1987™
NDC# 55714-2246-1

Insomnia

Formulated for associated symptoms such as the inability to fall asleep as well as return to sleep after waking, frequent waking and restlessness.

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: Absinthium 10x, Anacardium orientale 10x, Arg. nit. 10x, Arsenicum alb. 10x, Belladonna 10x, Bryonia 10x, Calc. carb. 10x, Camphora 10x, Chamomilla 10x, Cimicifuga 10x, Cinchona 10x, Coffea cruda 10x, Cypripedium 10x, Gelsemium 10x, Humulus 10x, Hyoscyamus 10x, Ignatia 10x, Kali brom. 10x, Nux vom. 10x, Passiflora 10x, Pulsatilla 10x, Scutellaria lateriflora 10x, Sepia 10x, Thuja occ. 10x, Passiflora 3x, Valeriana 3x.
Inactive Ingredients: USP Purified water; USP Gluten-free, non-GMO, organic cane dispensing alcohol 20%.

Stock# **N071** Lot#

INSOMNIA

absinthium, anacardium orientale, arg. nit., arsenicum alb., belladonna, bryonia, calc. carb., camphora, chamomilla, cimicifuga, cinchona, coffea cruda, cypripedium, gelsemium, humulus, hyoscyamus, ignatia, kali brom., nux vom., passiflora, pulsatilla, scutellaria lateriflora, sepia, thuja occ., valeriana liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2246
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Wormwood (UNII: F84709P2XV) (Wormwood - UNII:F84709P2XV)	Wormwood	10 [hp_X] in 1 mL
Semecarpus Anacardium Juice (UNII: Y0F0BU8RDU) (Semecarpus Anacardium Juice -	Semecarpus Anacardium	10 [hp_X]

UNII:Y0F0BU8RDU)	Juice	in 1 mL
Silver Nitrate (UNII: 95IT3W8JZE) (Silver Cation - UNII:57N7B0K90A)	Silver Nitrate	10 [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
Oyster Shell Calcium Carbonate, Crude (UNII: 2E32821G6I) (Oyster Shell Calcium Carbonate, Crude - UNII:2E32821G6I)	Oyster Shell Calcium Carbonate, Crude	10 [hp_X] in 1 mL
Camphor (natural) (UNII: N20HL7Q941) (Camphor (natural) - UNII:N20HL7Q941)	Camphor (natural)	10 [hp_X] in 1 mL
Matricaria Recutita (UNII: G0R4UBI2ZZ) (Matricaria Recutita - UNII:G0R4UBI2ZZ)	Matricaria Recutita	10 [hp_X] in 1 mL
Black Cohosh (UNII: K73E24S6X9) (Black Cohosh - UNII:K73E24S6X9)	Black Cohosh	10 [hp_X] in 1 mL
Cinchona Officinalis Bark (UNII: S003A158SB) (Cinchona Officinalis Bark - UNII:S003A158SB)	Cinchona Officinalis Bark	10 [hp_X] in 1 mL
Arabica Coffee Bean (UNII: 3SW678MX72) (Arabica Coffee Bean - UNII:3SW678MX72)	Arabica Coffee Bean	10 [hp_X] in 1 mL
Cypripedium Parvifolium Root (UNII: 21Y9GZ1LZA) (Cypripedium Parvifolium Root - UNII:21Y9GZ1LZA)	Cypripedium Parvifolium Root	10 [hp_X] in 1 mL
Gelsemium Sempervirens Root (UNII: 639KR60Q1Q) (Gelsemium Sempervirens Root - UNII:639KR60Q1Q)	Gelsemium Sempervirens Root	10 [hp_X] in 1 mL
Hops (UNII: 01G73H6H83) (Hops - UNII:01G73H6H83)	Hops	10 [hp_X] in 1 mL
Hyoscyamus Niger (UNII: 4WRK2153H3) (Hyoscyamus Niger - UNII:4WRK2153H3)	Hyoscyamus Niger	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
Potassium Bromide (UNII: OSD78555ZM) (Bromide Ion - UNII:952902IX06)	Potassium Bromide	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
Passiflora Incarnata Flowering Top (UNII: CLF5YFS11O) (Passiflora Incarnata Flowering Top - UNII:CLF5YFS11O)	Passiflora Incarnata Flowering Top	10 [hp_X] in 1 mL
Pulsatilla Vulgaris (UNII: I76KB35JEV) (Pulsatilla Vulgaris - UNII:I76KB35JEV)	Pulsatilla Vulgaris	10 [hp_X] in 1 mL
Scutellaria Lateriflora (UNII: 7BP4DH5PDC) (Scutellaria Lateriflora - UNII:7BP4DH5PDC)	Scutellaria Lateriflora	10 [hp_X] in 1 mL
Sepia Officinalis Juice (UNII: QDL83WN8C2) (Sepia Officinalis Juice - UNII:QDL83WN8C2)	Sepia Officinalis Juice	10 [hp_X] in 1 mL
Thuja Occidentalis Leafy Twig (UNII: 1NT28V9397) (Thuja Occidentalis Leafy Twig - UNII:1NT28V9397)	Thuja Occidentalis Leafy Twig	10 [hp_X] in 1 mL
Valerian (UNII: JWF5YAW3QW) (Valerian - UNII:JWF5YAW3QW)	Valerian	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:55714-2246-1	29.57 mL in 1 BOTTLE, GLASS		

2	NDC:55714-2246-2	59.14 mL in 1 BOTTLE, GLASS		
3	NDC:55714-2246-0	.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(55714-2246)

Revised: 3/2011

Newton Laboratories, Inc.