

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

PRODUCT NAME & INDICATIONS 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.

DIRECTION 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.

ACTIVE INGREDIENT SECTION

Absinthium 15x, Anacardium occidentale 15x, Arg. nit. 15x, Arsenicum alb. 15x, Belladonna 15x, Bryonia 15x, Calc. carb. 15x, Camphora 15x, Chamomilla 15x, Cimicifuga 15x, Cinchona 15x, Coffea cruda 15x, Cypripedium 15x, Gelsemium 15x, Humulus 15x, Hyoscyamus 15x, Ignatia 15x, Kali brom. 15x, Nux vom. 15x, Passiflora 15x, Pulsatilla 15x, Scutellaria lateriflora 15x, Sepia 15x, Thuja occ. 15x, Passiflora 8x, Valeriana 8x, Passiflora 3x, Valeriana 3x.

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.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# 55714-4404-1

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)

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 hour before bedtime, and then again at bedtime. Repeat as needed or as directed by a healthcare professional.
Active Ingredients: Absinthium 15x, Anacardium occidentale 15x, Arg. nit. 15x, Arsenicum alb. 15x, Belladonna 15x, Bryonia 15x, Calc. carb. 15x, Camphora 15x, Chamomilla 15x, Cimicifuga 15x, Cinchona 15x, Coffea cruda 15x, Cypripedium 15x, Gelsemium 15x, Humulus 15x, Hyoscyamus 15x, Ignatia 15x, Kali brom. 15x, Nux vom. 15x, Passiflora 15x, Pulsatilla 15x, Scutellaria lateriflora 15x, Sepia 15x, Thuja occ. 15x, Passiflora 8x, Valeriana 8x, Passiflora 3x, Valeriana 3x.
Inactive Ingredients: USP Purified water; USP Gluten-free, non-GMO, organic cane dispensing alcohol 20%.

Stock# R003 Lot#

INSOMNIA

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

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:55714-4404
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Wormwood (UNII: F84709P2XV) (Wormwood - UNII:F84709P2XV)	Wormwood	15 [hp_X] in 1 mL
Anacardium Occidentale Fruit (UNII: 4A10JR4E7E) (Anacardium Occidentale Fruit - UNII:4A10JR4E7E)	Anacardium Occidentale Fruit	15 [hp_X] in 1 mL
Silver Nitrate (UNII: 95IT3W8JZE) (Silver Cation - UNII:57N7B0K90A)	Silver Nitrate	15 [hp_X] in 1 mL
Arsenic Trioxide (UNII: S7V92P67HO) (Arsenic Trioxide - UNII:S7V92P67HO)	Arsenic Trioxide	15 [hp_X] in 1 mL
Atropa Belladonna (UNII: WQZ3G9PF0H) (Atropa Belladonna - UNII:WQZ3G9PF0H)	Atropa Belladonna	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
Oyster Shell Calcium Carbonate, Crude (UNII: 2E32821G6I) (Oyster Shell Calcium Carbonate, Crude - UNII:2E32821G6I)	Oyster Shell Calcium Carbonate, Crude	15 [hp_X] in 1 mL
Camphor (natural) (UNII: N20HL7Q941) (Camphor (natural) - UNII:N20HL7Q941)	Camphor (natural)	15 [hp_X] in 1 mL
Matricaria Recutita (UNII: G0R4UBI2ZZ) (Matricaria Recutita - UNII:G0R4UBI2ZZ)	Matricaria Recutita	15 [hp_X] in 1 mL
Black Cohosh (UNII: K73E24S6X9) (Black Cohosh - UNII:K73E24S6X9)	Black Cohosh	15 [hp_X] in 1 mL
Cinchona Officinalis Bark (UNII: S003A158SB) (Cinchona Officinalis Bark - UNII:S003A158SB)	Cinchona Officinalis Bark	15 [hp_X] in 1 mL
Arabica Coffee Bean (UNII: 3SW678MX72) (Arabica Coffee Bean - UNII:3SW678MX72)	Arabica Coffee Bean	15 [hp_X] in 1 mL
Cypripedium Parvifolium Root (UNII: 21Y9GZ1LZA) (Cypripedium Parvifolium Root - UNII:21Y9GZ1LZA)	Cypripedium Parvifolium Root	15 [hp_X] in 1 mL
Gelsemium Sempervirens Root (UNII: 639KR60Q1Q) (Gelsemium Sempervirens Root - UNII:639KR60Q1Q)	Gelsemium Sempervirens Root	15 [hp_X] in 1 mL
Hops (UNII: 01G73H6H83) (Hops - UNII:01G73H6H83)	Hops	15 [hp_X] in 1 mL
Hyoscyamus Niger (UNII: 4WRK2153H3) (Hyoscyamus Niger - UNII:4WRK2153H3)	Hyoscyamus Niger	15 [hp_X] in 1 mL
Strychnos Ignatii Seed (UNII: 1NM3M2487K) (Strychnos Ignatii Seed - UNII:1NM3M2487K)	Strychnos Ignatii Seed	15 [hp_X] in 1 mL
Potassium Bromide (UNII: OSD78555ZM) (Potassium Cation - UNII:295O53K152)	Potassium Bromide	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
Passiflora Incarnata Flowering Top (UNII: CLF5YFS11O) (Passiflora Incarnata Flowering Top - UNII:CLF5YFS11O)	Passiflora Incarnata Flowering Top	15 [hp_X] in 1 mL
Pulsatilla Vulgaris (UNII: I76KB35JEV) (Pulsatilla Vulgaris - UNII:I76KB35JEV)	Pulsatilla Vulgaris	15 [hp_X] in 1 mL
Scutellaria Lateriflora (UNII: 7BP4DH5PDC) (Scutellaria Lateriflora - UNII:7BP4DH5PDC)	Scutellaria Lateriflora	15 [hp_X] in 1 mL
Sepia Officinalis Juice (UNII: QDL83WN8C2) (Sepia Officinalis Juice - UNII:QDL83WN8C2)	Sepia Officinalis Juice	15 [hp_X] in 1 mL
Thuja Occidentalis Leafy Twig (UNII: 1NT28V9397) (Thuja Occidentalis Leafy Twig - UNII:1NT28V9397)	Thuja Occidentalis Leafy Twig	15 [hp_X] in 1 mL
Passiflora Incarnata Flowering Top (UNII: CLF5YFS11O) (Passiflora Incarnata Flowering Top - UNII:CLF5YFS11O)	Passiflora Incarnata Flowering Top	8 [hp_X] in 1 mL
Valerian (UNII: JWF5YAW3QW) (Valerian - UNII:JWF5YAW3QW)	Valerian	8 [hp_X] in 1 mL
Passiflora Incarnata Flowering Top (UNII: CLF5YFS11O) (Passiflora Incarnata Flowering Top - UNII:CLF5YFS11O)	Passiflora Incarnata Flowering Top	3 [hp_X] in 1 mL
Valerian (UNII: JWF5YAW3QW) (Valerian - UNII:JWF5YAW3QW)	Valerian	3 [hp_X] in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-4404-1	29.57 mL in 1 BOTTLE, GLASS		
2	NDC:55714-4404-2	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, API MANUFACTURE

Revised: 6/2011

Newton Laboratories, Inc.