

**I-SLEEP- 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.*

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**I-Sleep 2568L**

**INDICATIONS & USAGE SECTION**

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

**DOSAGE & ADMINISTRATION SECTION**

**Directions:** Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) one hour before bedtime, and then again at bedtime. Repeat as needed or as directed by a health professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

**OTC - ACTIVE INGREDIENT SECTION**

Equal parts of Passiflora incarnata 6x, Valeriana officinalis 6x, Absinthium 15x, Anacardium orientale 15x, Argentum nitricum 15x, Arsenicum album 15x, Belladonna 15x, Bryonia 15x, Calcarea carbonica 15x, Camphora 15x, Chamomilla 15x, Cimicifuga racemosa 15x, Cinchona officinalis 15x, Coffea cruda 15x, Cypripedium pubescens 15x, Gelsemium sempervirens 15x, Humulus lupulus 15x, Hyoscyamus niger 15x, Ignatia amara 15x, Kali bromatum 15x, Nux vomica 15x, Passiflora 15x, Pulsatilla 15x, Scutellaria 15x, Sepia 15x, Thuja occ. 15x.

**OTC - PURPOSE SECTION**

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

**INACTIVE INGREDIENT SECTION**

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

**QUESTIONS SECTION**

newtonlabs.net - Questions? 800.448.7256

Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 30013

## WARNINGS SECTION

**WARNINGS: Keep out of reach of children. Do not use** if tamper-evident seal is broken or missing. If symptoms worsen or persist for more than a few days, consult a doctor. If **pregnant or breast-feeding**, ask a doctor before use.

## OTC - PREGNANCY OR BREAST FEEDING SECTION

If **pregnant or breast-feeding**, ask a doctor before use.

## OTC - KEEP OUT OF REACH OF CHILDREN SECTION

**Keep out of reach of children.**

## PACKAGE LABEL

newtonlabs.net ~ Questions? 800.448.7256  
Newton Laboratories, Inc. FDA Est # 1051203 • Conyers, GA 30013  
Label statements have not been reviewed by the FDA.

**WARNINGS:** Keep out of reach of children. Do not use if tamper-evident seal is broken or missing. If symptoms worsen or persist for more than a few days, consult a doctor. If pregnant or breast-feeding, ask a doctor before use.

**NEWTON**  
homeopathics™  
Since 1987

NDC#  
55714-2568-1

**I-Sleep**

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

**1 FL OZ (30 ML)**

**Directions:** Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) one hour before bedtime, and then again at bedtime. Repeat as needed or as directed by a health professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

**Active Ingredients:** Equal parts of Passiflora 6x, Valeriana 6x, Absinthium 15x, Anacardium 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 15x, Sepia 15x, Thuja occ. 15x.

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

Stock# N071 Lot#

## I-SLEEP

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**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55714-2568
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>WORMWOOD</b> (UNII: F84709P2XV) (WORMWOOD - UNII:F84709P2XV)	WORMWOOD	15 [hp_X] in 1 mL
<b>SEMECARPUS ANACARDIUM JUICE</b> (UNII: Y0F0BU8RDU) (SEMECARPUS ANACARDIUM JUICE - UNII:Y0F0BU8RDU)	SEMECARPUS ANACARDIUM JUICE	15 [hp_X] in 1 mL
<b>SILVER NITRATE</b> (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A)	SILVER NITRATE	15 [hp_X] in 1 mL
<b>ARSENIC TRIOXIDE</b> (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	15 [hp_X] in 1 mL
<b>ATROPA BELLADONNA</b> (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	15 [hp_X] in 1 mL
<b>BRYONIA ALBA ROOT</b> (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	15 [hp_X] in 1 mL
<b>OYSTER SHELL CALCIUM CARBONATE, CRUDE</b> (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	15 [hp_X] in 1 mL
<b>CAMPHOR (NATURAL)</b> (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	15 [hp_X] in 1 mL
<b>MATRICARIA CHAMOMILLA</b> (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	15 [hp_X] in 1 mL
<b>BLACK COHOSH</b> (UNII: K73E24S6X9) (BLACK COHOSH - UNII:K73E24S6X9)	BLACK COHOSH	15 [hp_X] in 1 mL
<b>CINCHONA OFFICINALIS BARK</b> (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB)	CINCHONA OFFICINALIS BARK	15 [hp_X] in 1 mL
<b>ARABICA COFFEE BEAN</b> (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	15 [hp_X] in 1 mL
<b>CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS ROOT</b> (UNII: 21Y9GZ1LZA) (CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS ROOT - UNII:21Y9GZ1LZA)	CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS ROOT	15 [hp_X] in 1 mL
<b>GELSEMIUM SEMPERVIRENS ROOT</b> (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	15 [hp_X] in 1 mL
<b>HOPS</b> (UNII: 01G73H6H83) (HOPS - UNII:01G73H6H83)	HOPS	15 [hp_X] in 1 mL
<b>HYOSCYAMUS NIGER</b> (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3)	HYOSCYAMUS NIGER	15 [hp_X] in 1 mL
<b>STRYCHNOS IGNATII SEED</b> (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	15 [hp_X] in 1 mL
<b>POTASSIUM BROMIDE</b> (UNII: OSD78555ZM) (BROMIDE ION - UNII:952902IX06)	POTASSIUM BROMIDE	15 [hp_X] in 1 mL
<b>STRYCHNOS NUX-VOMICA SEED</b> (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	15 [hp_X] in 1 mL
<b>PASSIFLORA INCARNATA FLOWERING TOP</b> (UNII: CLF5YFS110) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS110)	PASSIFLORA INCARNATA FLOWERING TOP	15 [hp_X] in 1 mL
<b>ANEMONE PULSATILLA</b> (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	15 [hp_X] in 1 mL
<b>SCUTELLARIA LATERIFLORA WHOLE</b> (UNII: 7BP4DH5PDC) (SCUTELLARIA LATERIFLORA WHOLE - UNII:7BP4DH5PDC)	SCUTELLARIA LATERIFLORA WHOLE	15 [hp_X] in 1 mL
<b>SEPIA OFFICINALIS JUICE</b> (UNII: QDL83WN8C2) (SEPIA OFFICINALIS JUICE - UNII:QDL83WN8C2)	SEPIA OFFICINALIS JUICE	15 [hp_X] in 1 mL
<b>THUJA OCCIDENTALIS LEAFY TWIG</b> (UNII: 1NT28V9397) (THUJA OCCIDENTALIS LEAFY TWIG - UNII:1NT28V9397)	THUJA OCCIDENTALIS LEAFY TWIG	15 [hp_X] in 1 mL
<b>VALERIAN</b> (UNII: IME5YAWB0M) (VALERIAN - UNII:IME5YAWB0M)	VALERIAN	6 [hp_X]

VALERIAN (UNII: JWF5TAW5QW) (VALERIAN - UNII:JWF5TAW5QW)	VALERIAN	in 1 mL
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### Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2568-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	02/01/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		02/01/2021	

**Labeler** - Newton Laboratories, Inc. (788793610)

**Registrant** - Newton Laboratories, Inc. (788793610)

### Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-2568)

Revised: 2/2021

Newton Laboratories, Inc.