

**STRESS LESS- aconitum nap., ambra, anacardium orientale, arg. nit., asafoetida, bryonia, chamomilla, cimicifuga, coffea cruda, cypridium, gelsemium, hyoscyamus, hypericum, ignatia, kali phos., nux vom., sambucus nig., strychninum, theridion, valeriana, passiflora liquid Stress Less, 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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**Stress Less**

## **QUESTIONS SECTION**

Manufactured for Stress Less, Inc., Atlanta, GA 30319

☐ **Questions? 800-555-3783**

## **INDICATIONS & USAGE SECTION**

**Stress Less:** Formulated for associated symptoms such as nervous discomfort, irritability, racing thoughts, restlessness, tension and worry.

## **DOSAGE & ADMINISTRATION SECTION**

**Directions:** Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) 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 3x, Valeriana 3x Aconitum nap. 15x, Ambra 15x, Anacard. or. 15x, Arg. nit. 15x, Asafoetida 15x, Bryonia 15x, Chamomilla 15x, Cimicifuga 15x, Coffea cruda 15x, Cypridium 15x, Gelsemium 15x, Hyoscyamus 15x, Hypericum 15x, Ignatia 15x, Kali phos. 15x, Nux vom. 15x, Sambucus nig. 15x, Strychninum 15x, Theridion 15x, Valeriana 15x, .

## **OTC - PURPOSE SECTION**

Formulated for associated symptoms such as nervous discomfort, irritability, racing thoughts, restlessness, tension and worry.

## **INACTIVE INGREDIENT SECTION**

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

## **WARNINGS SECTION**

**Warning: 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**

**STRESS LESS**

aconitum nap., ambra, anacardium orientale, arg. nit., asafoetida, bryonia, chamomilla, cimicifuga, coffea cruda, cypripedium, gelsemium, hyoscyamus, hypericum, ignatia, kali phos., nux vom., sambucus nig., strychninum, theridion, valeriana, passiflora liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67840-0001
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	15 [hp_X] in 1 mL
AMBERGRIS (UNII: XTC0D02P6C) (AMBERGRIS - UNII:XTC0D02P6C)	AMBERGRIS	15 [hp_X] in 1 mL
SEMECARPUS ANACARDIUM JUICE (UNII: Y0F0BU8RDU) (SEMECARPUS ANACARDIUM JUICE - UNII:Y0F0BU8RDU)	SEMECARPUS ANACARDIUM JUICE	15 [hp_X] in 1 mL
SILVER NITRATE (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A)	SILVER NITRATE	15 [hp_X] in 1 mL
ASAFETIDA (UNII: W9FZA51AS1) (ASAFETIDA - UNII:W9FZA51AS1)	ASAFETIDA	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

<b>MATRICARIA RECUTITA</b> (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	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>ARABICA COFFEE BEAN</b> (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	15 [hp_X] in 1 mL
<b>CYPRIPEDIUM PARVIFOLUM ROOT</b> (UNII: 21Y9GZ1LZA) (CYPRIPEDIUM PARVIFOLUM ROOT - UNII:21Y9GZ1LZA)	CYPRIPEDIUM PARVIFOLUM 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>HYOSCYAMUS NIGER</b> (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3)	HYOSCYAMUS NIGER	15 [hp_X] in 1 mL
<b>HYPERICUM PERFORATUM</b> (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	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 PHOSPHATE, DIBASIC</b> (UNII: CI71S98N1Z) (PHOSPHATE ION - UNII:NK08V8K8HR)	POTASSIUM PHOSPHATE, DIBASIC	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>SAMBUCUS NIGRA FLOWERING TOP</b> (UNII: CT03BSA18U) (SAMBUCUS NIGRA FLOWERING TOP - UNII:CT03BSA18U)	SAMBUCUS NIGRA FLOWERING TOP	15 [hp_X] in 1 mL
<b>STRYCHNINE</b> (UNII: H9Y79VD43J) (STRYCHNINE - UNII:H9Y79VD43J)	STRYCHNINE	15 [hp_X] in 1 mL
<b>THERIDION CURASSAVICUM</b> (UNII: 9Z8D3HEM8L) (THERIDION CURASSAVICUM - UNII:9Z8D3HEM8L)	THERIDION CURASSAVICUM	15 [hp_X] in 1 mL
<b>VALERIAN</b> (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	15 [hp_X] in 1 mL
<b>PASSIFLORA INCARNATA FLOWERING TOP</b> (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O)	PASSIFLORA INCARNATA FLOWERING TOP	3 [hp_X] in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67840-0001-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	01/15/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/15/2018	

**Labeler** - Stress Less, Inc. (926429432)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(67840-0001)

Revised: 1/2018

Stress Less, Inc.