

CALM ANXIETY AND STRESS- clematis vitalba, flos, helianthemum nummularium, flos, impatiens glandulifera, flos, ornithogalum umbellatum, flos, passiflora incarnata, angelica sinensis, argentum nitricum, cacao, lithium carbonicum, prunus cerasifera, flos, valeriana officinalis, piper methysticum, glandula suprarenalis suis, aconitum napellus, anacardium orientale, arsenicum album, calcarea carbonica, cocculus indicus, ignatia amara, gelsemium sempervirens liquid
Pro Weight Loss 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.

DRUG FACTS:

ACTIVE INGREDIENTS:

Clematis Vitalba, Flos 3X, Helianthemum Nummularium, Flos 3X, Impatiens Glandulifera, Flos 3X, Ornithogalum Umbellatum, Flos 3X, Passiflora Incarnata 3X, Angelica Sinensis 6X, Argentum Nitricum 6X, Cacao 6X, Lithium Carbonicum 6X, Prunus Cerasifera, Flos 6X, Valeriana Officinalis 6X, Piper Methysticum 7X, Glandula Suprarenalis Suis 8X, Aconitum Napellus 12X, Anacardium Orientale 12X, Arsenicum Album 12X, Calcarea Carbonica 12X, Cocculus Indicus 12X, Ignatia Amara 12X, Gelsemium Sempervirens 12X, 30X.

HOMEOPATHIC INDICATIONS:

For temporary relief of symptoms related to stress including mild anxiousness, worry, overwhelm, and mild fear.**

**These statements are based upon traditional homeopathic principles. They have not been reviewed by the Food and Drug Administration.

WARNINGS:

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

If pregnant or breast-feeding, ask a healthcare professional before use.

Tamper seal: *sealed for your protection.*

Do not use if seal is broken or missing.

KEEP OUT OF REACH OF CHILDREN:

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

1-10 drops under the tongue, 3 times a day or as directed by your health professional. Consult a physician for use in children under 12 years of age.

HOMEOPATHIC INDICATIONS:

For temporary relief of symptoms related to stress including mild anxiousness, worry, overwhelm, and mild fear.**

**These statements are based upon traditional homeopathic principles. They have not been reviewed by the Food and Drug Administration.

INACTIVE INGREDIENTS:

demineralized water, 25% ethanol

QUESTIONS:

Distributed by

Pro Weight Loss Inc., 94 Boylston Cir.

Shrewsbury, MA 01545 • 877-323-0107

PACKAGE LABEL DISPLAY:

NDC 70558-0010-1

Pro Weight Loss

HOMEOPATHIC

Calm

Anxiety and Stress

1 FL OZ (30 ml)

WARNINGS:

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. **If pregnant or breast-feeding, ask a healthcare professional before use.**
 Tamper seal: *sealed for your protection.*
 Do not use if seal is broken or missing.

DIRECTIONS:

1-10 drops under the tongue, 3 times a day or as directed by your health professional. Consult a physician for use in children under 12 years of age.

HOMEOPATHIC INDICATIONS:

For the temporary relief of the symptoms related to stress including mild anxiousness, worry, overwhelm, and mild fear.**

Distributed by

Pro Weight Loss Inc., 94 Boylston Cir.
 Shrewsbury, MA 01545 • 877-323-0107

NDC 70558-0010-1

**HOMEOPATHIC**

Calm

Anxiety and Stress

1 FL OZ (30 ml)

INACTIVE INGREDIENTS: demineralized water, 25% ethanol

ACTIVE INGREDIENTS:

Clematis Vit, Flos 3X, Helianthemum Num Flos 3X, Impatiens Glan Flos 3X, Ornithogalum Umbellatum, Flos 3X, Passiflora 3X, Angelica Sin 6X, Arg Nit 6X, Cacao 6X, Lithium Carb 6X, Prunus Cera Flos 6X, Valeriana 6X, Piper Meth 7X, Glandula Suprarenalis Suis 8X, Aconitum Nap 12X, Anacardium 12X, Arsenicum Alb 12X, Calc Carb 12X, Cocculus 12X, Ignatia 12X, Gelsemium 12X, 30X.

**These statements are based upon traditional homeopathic principles. They have not been reviewed by the Food and Drug Administration.

LOT:

CALM ANXIETY AND STRESS

clematis vitalba, flos, helianthemum nummularium, flos, impatiens glandulifera, flos, ornithogalum umbellatum, flos, passiflora incarnata, angelica sinensis, argentum nitricum, cacao, lithium carbonicum, prunus cerasifera, flos, valeriana officinalis, piper methysticum, glandula suprarenalis suis, aconitum napellus, anacardium orientale, arsenicum album, calcarea carbonica, cocculus indicus, ignatia amara, gelsemium sempervirens liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70558-0010
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLEMATIS VITALBA FLOWER (UNII: 7SCP4N87CI) (CLEMATIS VITALBA FLOWER - UNII:7SCP4N87CI)	CLEMATIS VITALBA FLOWER	3 [hp_X] in 1 mL
HELIANTHEMUM NUMMULARIUM FLOWER (UNII: 51BRR32WPP) (HELIANTHEMUM NUMMULARIUM FLOWER - UNII:51BRR32WPP)	HELIANTHEMUM NUMMULARIUM FLOWER	3 [hp_X] in 1 mL
IMPATIENS GLANDULIFERA FLOWER (UNII: AJU5O1A5ZV) (IMPATIENS GLANDULIFERA FLOWER - UNII:AJU5O1A5ZV)	IMPATIENS GLANDULIFERA FLOWER	3 [hp_X] in 1 mL
ORNITHOGALUM UMBELLATUM FLOWERING TOP (UNII: CZD6M4PY4B) (ORNITHOGALUM UMBELLATUM FLOWERING TOP - UNII:CZD6M4PY4B)	ORNITHOGALUM UMBELLATUM FLOWERING TOP	3 [hp_X] in 1 mL
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS110) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS110)	PASSIFLORA INCARNATA FLOWERING TOP	3 [hp_X] in 1 mL
ANGELICA SINENSIS ROOT (UNII: B66F4574UG) (ANGELICA SINENSIS ROOT - UNII:B66F4574UG)	ANGELICA SINENSIS ROOT	6 [hp_X] in 1 mL
SILVER NITRATE (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A)	SILVER NITRATE	6 [hp_X] in 1 mL
COCOA (UNII: D9108TZ9KG) (COCOA - UNII:D9108TZ9KG)	COCOA	6 [hp_X] in 1 mL
LITHIUM CARBONATE (UNII: 2BMD2GNA4V) (LITHIUM CATION - UNII:8H8Z5UER66)	LITHIUM CARBONATE	6 [hp_X] in 1 mL

PRUNUS CERASIFERA FLOWER (UNII: 0KD7R09EAS) (PRUNUS CERASIFERA FLOWER - UNII:0KD7R09EAS)	PRUNUS CERASIFERA FLOWER	6 [hp_X] in 1 mL
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	6 [hp_X] in 1 mL
MACROPIPER METHYSTICUM ROOT (UNII: BOW48C81XP) (MACROPIPER METHYSTICUM ROOT - UNII:BOW48C81XP)	MACROPIPER METHYSTICUM ROOT	7 [hp_X] in 1 mL
SUS SCROFA ADRENAL GLAND (UNII: 398IYQ16YV) (SUS SCROFA ADRENAL GLAND - UNII:398IYQ16YV)	SUS SCROFA ADRENAL GLAND	8 [hp_X] in 1 mL
ACONITUM NAPELLUS WHOLE (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS WHOLE	12 [hp_X] in 1 mL
SEMECARPUS ANACARDIUM JUICE (UNII: Y0F0BU8RDU) (SEMECARPUS ANACARDIUM JUICE - UNII:Y0F0BU8RDU)	SEMECARPUS ANACARDIUM JUICE	12 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	12 [hp_X] in 1 mL
OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	12 [hp_X] in 1 mL
ANAMIRTA COCCULUS SEED (UNII: 810258W28U) (ANAMIRTA COCCULUS SEED - UNII:810258W28U)	ANAMIRTA COCCULUS SEED	12 [hp_X] in 1 mL
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	12 [hp_X] in 1 mL
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	12 [hp_X] in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70558-0010-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	07/29/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/29/2021	

Labeler - Pro Weight Loss Inc. (080166665)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(70558-0010) , api manufacture(70558-0010) , label(70558-0010) , pack(70558-0010)

Revised: 1/2023

Pro Weight Loss Inc.