

DISTRESS-MOOD-SADNESS- angelica sinensis radix, aralia quinquefolia, arg. nit., arsenicum alb., berber. aqui., capsicum , cinchona, digitalis, gelsemium, hypericum, ignatia, iodum, kali brom., kali carb., mag. phos., nat. carb., nat. mur., phosphorus, salix nigra, sanguinaria, sepia, stramonium, echinacea, ginkgo 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.

Distress 4771L

INDICATIONS & USAGE SECTION

Formulated for associated symptoms such as irritability, grief, despondency, difficult concentration, oversensitivity and prolonged sadness.

DOSAGE & ADMINISTRATION SECTION

Directions: Ages 12 and up, take 6 drops by mouth (ages 6 to 11, give 3 drops) as needed or as directed by a health professional. **Warning: If symptoms worsen or persist, especially if suicidal thoughts are present, consult a licensed health professional.**

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Echinacea 11x, Ginkgo 11x, Angelica sin. 20x, Aralia quin. 20x, Arg. nit. 20x, Arsenicum alb. 20x, Berber. aqui. 20x, Capsicum 20x, Cinchona 20x, Digitalis 20x, Gelsemium 20x, Hypericum 20x, Ignatia 20x, Iodium 20x, Kali brom. 20x, Kali carb. 20x, Mag. phos. 20x, Nat. carb. 20x, Nat. mur. 20x, Phos. 20x, Salix nigra 20x, Sanguinaria 20x, Sepia 20x, Stramonium 20x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as irritability, grief, despondency, difficult concentration, oversensitivity and prolonged sadness.

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 missing or broken. If symptoms 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
PRO

NDC#
55714-4771-1

**Distress~Mood
~Sadness**

Formulated for associated symptoms such as irritability, grief, despondency, difficult concentration, oversensitivity and prolonged sadness.

1 FL OZ (30 ML)

Dispensed by health professionals - not sold over-the-counter.
Directions: Ages 12 and up, take 6 drops by mouth (ages 6 to 11, give 3 drops) as needed or as directed by a health professional.
Warning: If symptoms worsen or persist, especially if suicidal thoughts are present, consult a licensed health professional.
Active Ingredients: Equal parts of Echinacea 11x, Ginkgo 11x, Angelica sin. 20x, Aralia quin. 20x, Arg. nit. 20x, Arsenicum alb. 20x, Berber. aqu. 20x, Capsicum 20x, Cinchona 20x, Digitalis 20x, Gelsemium 20x, Hypericum 20x, Ignatia 20x, Iodum 20x, Kali brom. 20x, Kali carb. 20x, Mag. phos. 20x, Nat. carb. 20x, Nat. mur. 20x, Phos. 20x, Salix nig. 20x, Sanguinaria 20x, Sepia 20x, Stramonium 20x.
Inactive Ingredients: USP Purified water; USP Gluten-free, non-GMO, organic cane alcohol 20%.

Stock# R084 Lot#

DISTRESS-MOOD-SADNESS

angelica sinensis radix, aralia quinquefolia, arg. nit., arsenicum alb., berber. aqu., capsicum, cinchona, digitalis, gelsemium, hypericum, ignatia, iodum, kali brom., kali carb., mag. phos., nat. carb., nat. mur., phosphorus, salix nigra, sanguinaria, sepia, stramonium, echinacea, ginkgo liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-4771
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	11 [hp_X] in 1 mL
GINKGO (UNII: 19FUJ2C58T) (GINKGO - UNII:19FUJ2C58T)	GINKGO	11 [hp_X] in 1 mL
BERBERIS AQUIFOLIUM ROOT BARK (UNII: VZJ9F3C3SB) (BERBERIS AQUIFOLIUM ROOT BARK - UNII:VZJ9F3C3SB)	BERBERIS AQUIFOLIUM ROOT BARK	20 [hp_X] in 1 mL
ANGELICA SINENSIS ROOT (UNII: B66F4574UG) (ANGELICA SINENSIS ROOT - UNII:B66F4574UG)	ANGELICA SINENSIS ROOT	20 [hp_X] in 1 mL
AMERICAN GINSENG (UNII: 8W75XCV52Q) (AMERICAN GINSENG - UNII:8W75XCV52Q)	AMERICAN GINSENG	20 [hp_X] in 1 mL

AMERICAN GINSENG (UNII: 8W75VCV53Q) (AMERICAN GINSENG - UNII:8W75VCV53Q)	AMERICAN GINSENG	20 [hp_X] in 1 mL
SILVER NITRATE (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A)	SILVER NITRATE	20 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	20 [hp_X] in 1 mL
CAPSICUM (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)	CAPSICUM	20 [hp_X] in 1 mL
CINCHONA OFFICINALIS BARK (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB)	CINCHONA OFFICINALIS BARK	20 [hp_X] in 1 mL
DIGITALIS (UNII: F1T8QT9U8B) (DIGITALIS - UNII:F1T8QT9U8B)	DIGITALIS	20 [hp_X] in 1 mL
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	20 [hp_X] in 1 mL
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	20 [hp_X] in 1 mL
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	20 [hp_X] in 1 mL
IODINE (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	20 [hp_X] in 1 mL
POTASSIUM BROMIDE (UNII: OSD78555ZM) (BROMIDE ION - UNII:952902IX06)	POTASSIUM BROMIDE	20 [hp_X] in 1 mL
POTASSIUM CARBONATE (UNII: BQN1B9B9HA) (CARBONATE ION - UNII:7UJQ5OPE7D)	POTASSIUM CARBONATE	20 [hp_X] in 1 mL
MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE (UNII: HF539G9L3Q) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE	20 [hp_X] in 1 mL
SODIUM CARBONATE (UNII: 45P3261C7T) (CARBONATE ION - UNII:7UJQ5OPE7D)	SODIUM CARBONATE	20 [hp_X] in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	20 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	20 [hp_X] in 1 mL
SALIX NIGRA BARK (UNII: QU52J3A5B3) (SALIX NIGRA BARK - UNII:QU52J3A5B3)	SALIX NIGRA BARK	20 [hp_X] in 1 mL
SANGUINARIA CANADENSIS ROOT (UNII: N9288CD508) (SANGUINARIA CANADENSIS ROOT - UNII:N9288CD508)	SANGUINARIA CANADENSIS ROOT	20 [hp_X] in 1 mL
SEPIA OFFICINALIS JUICE (UNII: QDL83WN8C2) (SEPIA OFFICINALIS JUICE - UNII:QDL83WN8C2)	SEPIA OFFICINALIS JUICE	20 [hp_X] in 1 mL
DATURA STRAMONIUM (UNII: G6W4F0V8Z3) (DATURA STRAMONIUM - UNII:G6W4F0V8Z3)	DATURA STRAMONIUM	20 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-4771-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/02/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		09/02/2018	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-4771)

Revised: 12/2020

Newton Laboratories, Inc.