

**RESTLESS LEG- mygale, agaricus musc., causticum, cinchona, conium, cuprum met., gelsemium, hyoscyamus, hypericum, kali carb., mag. carb., merc. viv., nux vom., plumb. met., rhus toxicodendron, secale, strychninum, tarentula hispana, valeriana, verbas cum, zinc. met., chamomilla, passiflora 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.

Restless 2554L

INDICATIONS & USAGE SECTION

Formulated for associated symptoms such as the constant need to move the legs and feet, cramping, jerking, twitching and trembling.

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 Chamomilla 6x, Passiflora incarnata 6x, Valeriana officinalis 6x, Agaricus muscarius 15x, Causticum 15x, Cinchona officinalis 15x, Conium maculatum 15x, Cuprum metallicum 15x, Gelsemium sempervirens 15x, Hyoscyamus niger 15x, Hypericum perforatum 15x, Kali carbonicum 15x, Magnesia carbonica 15x, Mercurius vivus 15x, Nux vomica 15x, Plumbum metallicum 15x, Rhus toxicodendron 15x, Secale cornutum 15x, Strychninum 15x, Tarentula hispana 15x, Valeriana officinalis 15x, Verbas cum thapsus 15x, Zincum metallicum 15x, Mygale 16x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as the constant need to move the legs and feet, cramping, jerking, twitching and trembling.

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

RESTLESS LEG

mygale, agaricus musc., causticum, cinchona, conium, cuprum met., gelsemium, hyoscyamus, hypericum, kali carb., mag. carb., merc. viv., nux vom., plumb. met., rhus toxicodendron, secale, strychninum, tarentula hispana, valeriana, verbasum, zinc. met., chamomilla, passiflora liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2554
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMANITA MUSCARIA FRUITING BODY (UNII: DIF0931037) (AMANITA MUSCARIA FRUITING BODY - UNII:DIF0931037)	AMANITA MUSCARIA FRUITING BODY	15 [hp_X] in 1 mL
AVICULARIA AVICULARIA (UNII: 8ZTK6T93B6) (AVICULARIA AVICULARIA - UNII:8ZTK6T93B6)	AVICULARIA AVICULARIA	16 [hp_X] in 1 mL
CAUSTICUM (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)	CAUSTICUM	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

CONIUM MACULATUM FLOWERING TOP (UNII: Q28R5GF371) (CONIUM MACULATUM FLOWERING TOP - UNII:Q28R5GF371)	CONIUM MACULATUM FLOWERING TOP	15 [hp_X] in 1 mL
COPPER (UNII: 789U1901C5) (COPPER - UNII:789U1901C5)	COPPER	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
HYOSCYAMUS NIGER (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3)	HYOSCYAMUS NIGER	15 [hp_X] in 1 mL
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	15 [hp_X] in 1 mL
POTASSIUM CARBONATE (UNII: BQN1B9B9HA) (CARBONATE ION - UNII:7UJQ5OPE7D)	POTASSIUM CARBONATE	15 [hp_X] in 1 mL
MAGNESIUM CARBONATE (UNII: 0E53J927NA) (CARBONATE ION - UNII:7UJQ5OPE7D)	MAGNESIUM CARBONATE	15 [hp_X] in 1 mL
MERCURY (UNII: FXS1BY2PGL) (MERCURY - UNII:FXS1BY2PGL)	MERCURY	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
LEAD (UNII: 2P299V784P) (LEAD - UNII:2P299V784P)	LEAD	15 [hp_X] in 1 mL
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	15 [hp_X] in 1 mL
CLAVICEPS PURPUREA SCLEROTIUM (UNII: 01G9XEA93N) (CLAVICEPS PURPUREA SCLEROTIUM - UNII:01G9XEA93N)	CLAVICEPS PURPUREA SCLEROTIUM	15 [hp_X] in 1 mL
STRYCHNINE (UNII: H9Y79VD43J) (STRYCHNINE - UNII:H9Y79VD43J)	STRYCHNINE	15 [hp_X] in 1 mL
LYCOSA TARANTULA (UNII: 86M454L2TT) (LYCOSA TARANTULA - UNII:86M454L2TT)	LYCOSA TARANTULA	15 [hp_X] in 1 mL
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	15 [hp_X] in 1 mL
VERBASCUM THAPSUS (UNII: C9TD27U172) (VERBASCUM THAPSUS - UNII:C9TD27U172)	VERBASCUM THAPSUS	15 [hp_X] in 1 mL
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	15 [hp_X] in 1 mL
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	6 [hp_X] in 1 mL
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O)	PASSIFLORA INCARNATA FLOWERING TOP	6 [hp_X] in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2554-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	08/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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unapproved homeopathic

08/01/2019

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-2554)

Revised: 1/2020

Newton Laboratories, Inc.