

BEDWETTING- echinacea, hydrastis canadensis, passiflora incarnata, valeriana officinalis, belladonna, cantharis, causticum, equisetum hyemale, ferrum metallicum, gelsemium sempervirens, humulus lupulus, kali phosphoricum, lycopodium clavatum, natrum muriaticum, plantago major, pulsatilla, rhus aromatica, sabal serrulata, thyroidinum, verbascum thapsus pellet

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.

Bedwetting 1721P

INDICATIONS & USAGE SECTION

Formulated for associated symptoms often related to fear, nervousness, muscle tone and trauma.

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Echinacea 6x, Hydrastis canadensis 6x, Passiflora incarnata 6x, Valeriana officinalis 6x, Belladonna 15x, Cantharis 15x, Causticum 15x, Equisetum hyemale 15x, Ferrum metallicum 15x, Gelsemium sempervirens 15x, Humulus lupulus 15x, Kali phosphoricum 15x, Lycopodium clavatum 15x, Natrum muriaticum 15x, Plantago major 15x, Pulsatilla 15x, Rhus aromatica 15x, Sabal serrulata 15x, Thyroidinum 15x, Verbascum thapsus 15x.

OTC - PURPOSE SECTION

Formulated for associated symptoms often related to fear, nervousness, muscle tone and trauma.

INACTIVE INGREDIENT SECTION

Gluten-free, non-GMO, organic beet-derived sucrose (lactose-free) pellets

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.

DOSAGE & ADMINISTRATION SECTION

Directions: Children, ages 0 to 11, give 3 pellets by mouth (ages 12 and up, give 6 pellets) one hour before bedtime, and then again at bedtime. Repeat as needed or as directed by a health professional. Under age 2, crush/dissolve pellets in purified water. Sensitive person begin with 1 pellet and gradually increase to full dose.

PACKAGE LABEL

newtonlabs.net ~ Questions? 800.448.7256
 Newton Laboratories, Inc. FDA Est# 1051203 • Compys, 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 Kids
 NDC# 55714-1721-1

Bedwetting
 Formulated for associated symptoms often related to fear, nervousness, muscle tone and trauma.

1 OZ (28 G)

Directions: Children, ages 0 to 11, give 3 pellets by mouth (ages 12 and up, give 6 pellets) one hour before bedtime, and then again at bedtime. Repeat as needed or as directed by a health professional. Under age 2, crush/dissolve pellets in purified water. Sensitive persons begin with 1 pellet and gradually increase to full dose.

Active Ingredients: Equal parts of Echinacea 6x, Hydrastis 6x, Passiflora 6x, Valeriana 6x, Belladonna 15x, Cantharis 15x, Causticum 15x, Equisetum hyem. 15x, Ferrum met. 15x, Gelsemium 15x, Humulus 15x, Kali phos. 15x, Lycopodium 15x, Nat. mur. 15x, Plantago 15x, Pulsatilla 15x, Rhus arom. 15x, Sabal 15x, Thyroidinum 15x, Verbasum 15x.

Inactive Ingredients: Gluten-free, non-GMO, organic beet-derived sucrose (lactose-free) pellets.

Stock# F044 Lot#

BEDWETTING

echinacea, hydrastis canadensis, passiflora incarnata, valeriana officinalis, belladonna, cantharis, causticum, equisetum hyemale, ferrum metallicum, gelsemium sempervirens, humulus lupulus, kali phosphoricum, lycopodium clavatum, natrum muriaticum, plantago major, pulsatilla, rhus aromatica, sabal serrulata, thyroidinum, verbasum thapsus pellet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-1721
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	6 [hp_X] in 1 g
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	6 [hp_X] in 1 g
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	15 [hp_X] in 1 g
LYTTA VESICATORIA (UNII: 3Q034RO3BT) (LYTTA VESICATORIA -	LYTTA VESICATORIA	15 [hp_X]

UNII:3Q034R03BT)	LITTA VESICATORIA	in 1 g
CAUSTICUM (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)	CAUSTICUM	15 [hp_X] in 1 g
EQUISETUM HYEMALE (UNII: 59677RXH25) (EQUISETUM HYEMALE - UNII:59677RXH25)	EQUISETUM HYEMALE	15 [hp_X] in 1 g
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	15 [hp_X] in 1 g
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	15 [hp_X] in 1 g
HOPS (UNII: 01G73H6H83) (HOPS - UNII:01G73H6H83)	HOPS	15 [hp_X] in 1 g
DIBASIC POTASSIUM PHOSPHATE (UNII: CI71S98N1Z) (POTASSIUM CATION - UNII:295O53K152)	DIBASIC POTASSIUM PHOSPHATE	15 [hp_X] in 1 g
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 g
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	15 [hp_X] in 1 g
PLANTAGO MAJOR (UNII: W2469WNO6U) (PLANTAGO MAJOR - UNII:W2469WNO6U)	PLANTAGO MAJOR	15 [hp_X] in 1 g
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	15 [hp_X] in 1 g
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	15 [hp_X] in 1 g
SAW PALMETTO (UNII: J7WWH9M8QS) (SAW PALMETTO - UNII:J7WWH9M8QS)	SAW PALMETTO	15 [hp_X] in 1 g
THYROID, UNSPECIFIED (UNII: 0B4FDL9I6P) (THYROID, UNSPECIFIED - UNII:0B4FDL9I6P)	THYROID, UNSPECIFIED	15 [hp_X] in 1 g
VERBASCUM THAPSUS (UNII: C9TD27U172) (VERBASCUM THAPSUS - UNII:C9TD27U172)	VERBASCUM THAPSUS	15 [hp_X] in 1 g
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O)	PASSIFLORA INCARNATA FLOWERING TOP	6 [hp_X] in 1 g
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	15 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-1721-1	28 g in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/01/2019	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-1721)

Revised: 11/2020

Newton Laboratories, Inc.