

**BEDWETTING - belladonna, cantharis, causticum, equisetum hyemale, ferrum metallicum, gelsemium, humulus, kali phos., lycopodium, nat.mur., plantago, pulsatilla, rhus aromatica, sabal, thyroidinum, verbascum, echinacea, hydrastis, passiflora, valeriana 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.

Bedwetting

INDICATIONS & USAGE SECTION

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

DOSAGE & ADMINISTRATION SECTION

Directions: ORAL USE ONLY - SHAKE WELL. Children, ages 0 to 11, give 3 drops orally (ages 12 and up, give 6 drops) one hour before bedtime, and then again at bedtime. Repeat as needed or as directed by a healthcare professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Belladonna 15x, Cantharis 15x, Causticum 15x, Equisetum hyemale 15x, Ferrum metallicum 15x, Gelsemium 15x, Humulus 15x, Kali phos. 15x, Lycopodium 15x, Nat.mur. 15x, Plantago 15x, Pulsatilla 15x, Rhus aromatica 15x, Sabal 15x, Thyroidinum 15x, Verbascum 15x, Echinacea 3x, Hydrastis 3x, Passiflora 3x, Valeriana 3x.

OTC - PURPOSE SECTION

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

INACTIVE INGREDIENT SECTION

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

QUESTIONS SECTION

www.newtonlabs.net Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 30012
Questions? 1.800.448.7256

WARNINGS SECTION

Warning: Do not use if tamper - evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.

OTC - PREGNANCY OR BREAST FEEDING SECTION

Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

PACKAGE LABEL

NEWTON
homeopathics
for Kids
Nurturing Naturally Since 1987™

NDC#
55714-1513-1

Bedwetting

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

1 fl oz (29.57 ml)

Directions: ORAL USE ONLY - SHAKE WELL.
Children, ages 0 to 11, give 3 drops orally (ages 12 and up, give 6 drops) one hour before bedtime, and then again at bedtime. Repeat as needed or as directed by a healthcare professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

Active Ingredients: Belladonna 15x, Cantharis 15x, Causticum 15x, Equisetum hyemale 15x, Ferrum metallicum 15x, Gelsemium 15x, Humulus 15x, Kali phos. 15x, Lycopodium 15x, Nat. mur. 15x, Plantago 15x, Pulsatilla 15x, Rhus aromatica 15x, Sabal 15x, Thyroidinum 15x, Verbascum 15x, Echinacea 3x, Hydrastis 3x, Passiflora 3x, Valeriana 3x.

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

Stock# F044 Lot#

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BEDWETTING

belladonna, cantharis, causticum, equisetum hyemale, ferrum metallicum, gelsemium, humulus, kali phos., lycopodium, nat.mur., plantago, pulsatilla, rhus aromatica, sabal, thyroidinum, verbascum, echinacea, hydrastis, passiflora, valeriana liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-1513
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Atropa Belladonna (UNII: WQZ3G9PF0H) (Atropa Belladonna - UNII:WQZ3G9PF0H)	Atropa Belladonna	15 [hp_X] in 1 mL
Lytta Vesicatoria (UNII: 3Q034RO3BT) (Lyttta Vesicatoria - UNII:3Q034RO3BT)	Lytta Vesicatoria	15 [hp_X] in 1 mL
Causticum (UNII: DD5FO1WKFU) (Causticum - UNII:DD5FO1WKFU)	Causticum	15 [hp_X] in 1 mL
Equisetum Hyemale (UNII: 59677RXH25) (Equisetum Hyemale - UNII:59677RXH25)	Equisetum Hyemale	15 [hp_X] in 1 mL
Iron (UNII: E1UOL152H7) (Iron - UNII:E1UOL152H7)	Iron	15 [hp_X] in 1 mL
Gelsemium Sempervirens Root (UNII: 639KR60Q1Q) (Gelsemium Sempervirens Root -	Gelsemium Sempervirens	15 [hp_X]

UNII:639KR60Q1Q)	Root	in 1 mL
Hops (UNII: 01G73H6H83) (Hops - UNII:01G73H6H83)	Hops	15 [hp_X] in 1 mL
Potassium Phosphate, Dibasic (UNII: C171S98N1Z) (Phosphate Ion - UNII:NK08V8K8HR)	Potassium Phosphate, Dibasic	15 [hp_X] in 1 mL
Lycopodium Clavatum Spore (UNII: C88X29Y479) (Lycopodium Clavatum Spore - UNII:C88X29Y479)	Lycopodium Clavatum Spore	15 [hp_X] in 1 mL
Sodium Chloride (UNII: 451W47IQ8X) (Chloride Ion - UNII:Q32ZN48698)	Sodium Chloride	15 [hp_X] in 1 mL
Plantago Major (UNII: W2469WNO6U) (Plantago Major - UNII:W2469WNO6U)	Plantago Major	15 [hp_X] in 1 mL
Pulsatilla Vulgaris (UNII: I76KB35JEV) (Pulsatilla Vulgaris - UNII:I76KB35JEV)	Pulsatilla Vulgaris	15 [hp_X] in 1 mL
Rhus Aromatica Root Bark (UNII: Q3H36W0J42) (Rhus Aromatica Root Bark - UNII:Q3H36W0J42)	Rhus Aromatica Root Bark	15 [hp_X] in 1 mL
Saw Palmetto (UNII: J7WWH9M8QS) (Saw Palmetto - UNII:J7WWH9M8QS)	Saw Palmetto	15 [hp_X] in 1 mL
Thyroid, Unspecified (UNII: 0B4FDL9I6P) (Thyroid, Unspecified - UNII:0B4FDL9I6P)	Thyroid, Unspecified	15 [hp_X] in 1 mL
Verbascum Thapsus (UNII: C9TD27U172) (Verbascum Thapsus - UNII:C9TD27U172)	Verbascum Thapsus	15 [hp_X] in 1 mL
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	3 [hp_X] in 1 mL
Goldenseal (UNII: ZW3Z11D0JV) (Goldenseal - UNII:ZW3Z11D0JV)	Goldenseal	3 [hp_X] in 1 mL
Passiflora Incarnata Flowering Top (UNII: CLF5YFS11O) (Passiflora Incarnata Flowering Top - UNII:CLF5YFS11O)	Passiflora Incarnata Flowering Top	3 [hp_X] in 1 mL
Valerian (UNII: JWF5YAW3QW) (Valerian - UNII:JWF5YAW3QW)	Valerian	3 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Alcohol (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-1513-1	29.57 mL in 1 BOTTLE, GLASS		
2	NDC:55714-1513-2	59.14 mL in 1 BOTTLE, GLASS		
3	NDC:55714-1513-0	.5 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/01/2011	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-1513)

Revised: 3/2011

Newton Laboratories, Inc.