

**PROSTATE- thyroidinum, baryta carb., berber. vulg., bryonia, calc. carb., cinchona, conium, digitalis, ferrum picricum, hydrastis, iodium, lycopodium, nux vom., pareira, pulsatilla, sabal, selenium, staphysag., thuja occ., trifolium pratense, echinacea, lappa, solidago 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.

Prostate 2503L

INDICATIONS & USAGE SECTION

Formulated for associated symptoms such as discomfort, frequent, incomplete or difficult urination, performance issues and other related symptoms.

DOSAGE & ADMINISTRATION SECTION

Directions: Adults, take 6 drops by mouth one to four times daily or as directed by a health professional. Sensitive persons begin with 1 drop and increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Echinacea 6x, Hydrastis canadensis 6x, Lappa major 6x, Solidago virgaurea 6x, Baryta carbonica 15x, Berberis vulgaris 15x, Bryonia 15x, Calcarea carbonica 15x, Cinchona officinalis 15x, Conium maculatum 15x, Digitalis purpurea 15x, Ferrum picricum 15x, Hydrastis canadensis 15x, Iodium 15x, Lycopodium clavatum 15x, Nux vomica 15x, Pareira brava 15x, Pulsatilla 15x, Sabal serrulata 15x, Selenium metallicum 15x, Staphysagria 15x, Thuja occidentalis 15x, Trifolium pratense 15x, Thyroidinum 15x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as discomfort, frequent, incomplete or difficult urination, performance issues and other related symptoms.

INACTIVE INGREDIENT SECTION

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

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 **Since 1987**

NDC# 55714-2503-1

Prostate

Formulated for associated symptoms such as discomfort, frequent, incomplete, or difficult urination, performance issues and other related symptoms.

1 FL OZ (30 ML)

Directions: Adults, take 6 drops by mouth one to four times daily or as directed by a health professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

Active Ingredients: Equal parts of Echinacea 6x, Hydrastis 6x, Lappa 6x, Solidago 6x, Baryta carb. 15x, Berber. vulg. 15x, Bryonia 15x, Calc. carb. 15x, Cinchona 15x, Conium 15x, Digitalis 15x, Ferrum pic. 15x, Hydrastis 15x, Iodium 15x, Lycopodium 15x, Nux vom. 15x, Pareira 15x, Pulsatilla 15x, Sabal 15x, Selenium 15x, Staphysag. 15x, Thuja occ. 15x, Thyroidinum 15x, Trifolium prat. 15x.

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

Stock# N022 Lot#

PROSTATE

thyroidinum, baryta carb., berber. vulg., bryonia, calc. carb., cinchona, conium, digitalis, ferrum picricum, hydrastis, iodium, lycopodium, nux vom., pareira, pulsatilla, sabal, selenium, staphysag., thuja occ., trifolium pratense, echinacea, lappa, solidago liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2503
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IODINE (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	15 [hp_X] in 1 mL
THYROID, UNSPECIFIED (UNII: 0B4FDL9I6P) (THYROID, UNSPECIFIED - UNII:0B4FDL9I6P)	THYROID, UNSPECIFIED	15 [hp_X] in 1 mL
BARIUM CARBONATE (UNII: 6P669D8HQ8) (BARIUM CATION - UNII:V64527HLN)	BARIUM CARBONATE	15 [hp_X] in 1 mL
BERBERIS VULGARIS ROOT BARK (UNII: 1TH8Q20J0U) (BERBERIS VULGARIS ROOT BARK - UNII:1TH8Q20J0U)	BERBERIS VULGARIS ROOT BARK	15 [hp_X] in 1 mL
BRYONIA ALBA ROOT (UNII: T71046X72P) (BRYONIA ALBA ROOT		15 [hp_X]

BRYONIA ALBA ROOT (UNII: 17J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	15 [hp_X] in 1 mL
OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	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
DIGITALIS (UNII: F1T8QT9U8B) (DIGITALIS - UNII:F1T8QT9U8B)	DIGITALIS	15 [hp_X] in 1 mL
FERRIC PICRATE (UNII: KZM8ZRY36A) (FERRIC CATION - UNII:91O4LML611)	FERRIC CATION	15 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	15 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	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
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	15 [hp_X] in 1 mL
CHONDRODENDRON TOMENTOSUM ROOT (UNII: 395A3P448Z) (CHONDRODENDRON TOMENTOSUM ROOT - UNII:395A3P448Z)	CHONDRODENDRON TOMENTOSUM ROOT	15 [hp_X] in 1 mL
SAW PALMETTO (UNII: J7WWH9M8QS) (SAW PALMETTO - UNII:J7WWH9M8QS)	SAW PALMETTO	15 [hp_X] in 1 mL
SELENIUM (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	15 [hp_X] in 1 mL
DELPHINIUM STAPHISAGRIA SEED (UNII: 00543AP1JV) (DELPHINIUM STAPHISAGRIA SEED - UNII:00543AP1JV)	DELPHINIUM STAPHISAGRIA SEED	15 [hp_X] in 1 mL
THUJA OCCIDENTALIS LEAFY TWIG (UNII: 1NT28V9397) (THUJA OCCIDENTALIS LEAFY TWIG - UNII:1NT28V9397)	THUJA OCCIDENTALIS LEAFY TWIG	15 [hp_X] in 1 mL
TRIFOLIUM PRATENSE FLOWER (UNII: 4JS0838828) (TRIFOLIUM PRATENSE FLOWER - UNII:4JS0838828)	TRIFOLIUM PRATENSE FLOWER	15 [hp_X] in 1 mL
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	6 [hp_X] in 1 mL
ARCTIUM LAPPAL ROOT (UNII: 597E9BI3Z3) (ARCTIUM LAPPAL ROOT - UNII:597E9BI3Z3)	ARCTIUM LAPPAL ROOT	6 [hp_X] in 1 mL
SOLIDAGO VIRGAUREA FLOWERING TOP (UNII: 5405K23S50) (SOLIDAGO VIRGAUREA FLOWERING TOP - UNII:5405K23S50)	SOLIDAGO VIRGAUREA FLOWERING TOP	6 [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:55714-2503-1	30 mL 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
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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(55714-2503)

Revised: 1/2020

Newton Laboratories, Inc.