

**PROSTATE - thyroidinum, baryta carb., berber. vulg., bryonia, calc. carb., cinchona, conium, digitalis, ferrum picricum, hydrastis, iodum, 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

INDICATIONS & USAGE SECTION

Prostate Formulated for associated symptoms such as enlargement, discomfort, frequent, incomplete or difficult urination and sexual dysfunction.

DOSAGE & ADMINISTRATION SECTION

Directions: ORAL USE ONLY - SHAKE WELL. Adults, take 6 drops orally one to four times daily or as directed by a healthcare professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Thyroidinum 15x, Baryta carb. 10x, Berber. vulg. 10x, Bryonia 10x, Calc. carb. 10x, Cinchona 10x, Conium 10x, Digitalis 10x, Ferrum picricum 10x, Hydrastis 10x, Iodium 10x, Lycopodium 10x, Nux vom. 10x, Pareira 10x, Pulsatilla 10x, Sabal 10x, Selenium 10x, Staphysag. 10x, Thuja occ. 10x, Trifolium pratense 10x, Echinacea 3x, Hydrastis 3x, Lappa 3x, Solidago 3x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as enlargement, discomfort, frequent, incomplete or difficult urination and sexual dysfunction.

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

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:55714-2242
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Thyroid, Unspecified (UNII: 0B4FDL9I6P) (Thyroid, Unspecified - UNII:0B4FDL9I6P)	Thyroid, Unspecified	15 [hp_X] in 1 mL
Barium Carbonate (UNII: 6P669D8HQ8) (Barium Cation - UNII:V645272HLN)	Barium Carbonate	10 [hp_X] in 1 mL
Berberis Vulgaris Root Bark (UNII: 1TH8Q20J0U) (Berberis Vulgaris Root Bark - UNII:1TH8Q20J0U)	Berberis Vulgaris Root Bark	10 [hp_X] in 1 mL
Bryonia Alba Root (UNII: T7J046YI2B) (Bryonia Alba Root - UNII:T7J046YI2B)	Bryonia Alba Root	10 [hp_X] in 1 mL
Oyster Shell Calcium Carbonate, Crude (UNII: 2E32821G6I) (Oyster Shell Calcium Carbonate, Crude - UNII:2E32821G6I)	Oyster Shell Calcium Carbonate, Crude	10 [hp_X] in 1 mL
Cinchona Officinalis Bark (UNII: S003A158SB) (Cinchona Officinalis Bark - UNII:S003A158SB)	Cinchona Officinalis Bark	10 [hp_X] in 1 mL

Conium Maculatum Flowering Top (UNII: Q28R5GF371) (Conium Maculatum Flowering Top - UNII:Q28R5GF371)	Conium Maculatum Flowering Top	10 [hp_X] in 1 mL
Digitalis (UNII: F1T8QT9U8B) (Digitalis - UNII:F1T8QT9U8B)	Digitalis	10 [hp_X] in 1 mL
Ferric Picrate (UNII: KZM8ZRY36A) (Ferric Cation - UNII:91O4LML611)	Ferric Picrate	10 [hp_X] in 1 mL
Goldenseal (UNII: ZW3Z11D0JV) (Goldenseal - UNII:ZW3Z11D0JV)	Goldenseal	10 [hp_X] in 1 mL
Iodine (UNII: 9679TC07X4) (Iodine - UNII:9679TC07X4)	Iodine	10 [hp_X] in 1 mL
Lycopodium Clavatum Spore (UNII: C88X29Y479) (Lycopodium Clavatum Spore - UNII:C88X29Y479)	Lycopodium Clavatum Spore	10 [hp_X] in 1 mL
Strychnos Nux-vomica Seed (UNII: 269XH13919) (Strychnos Nux-vomica Seed - UNII:269XH13919)	Strychnos Nux-vomica Seed	10 [hp_X] in 1 mL
Chondrodendron Tomentosum Root (UNII: 395A3P448Z) (Chondrodendron Tomentosum Root - UNII:395A3P448Z)	Chondrodendron Tomentosum Root	10 [hp_X] in 1 mL
Pulsatilla Vulgaris (UNII: I76KB35JEV) (Pulsatilla Vulgaris - UNII:I76KB35JEV)	Pulsatilla Vulgaris	10 [hp_X] in 1 mL
Saw Palmetto (UNII: J7WWH9M8QS) (Saw Palmetto - UNII:J7WWH9M8QS)	Saw Palmetto	10 [hp_X] in 1 mL
Selenium (UNII: H6241UJ22B) (Selenium - UNII:H6241UJ22B)	Selenium	10 [hp_X] in 1 mL
Delphinium Staphisagria Seed (UNII: 00543APIJV) (Delphinium Staphisagria Seed - UNII:00543APIJV)	Delphinium Staphisagria Seed	10 [hp_X] in 1 mL
Thuja Occidentalis Leafy Twig (UNII: 1NT28V9397) (Thuja Occidentalis Leafy Twig - UNII:1NT28V9397)	Thuja Occidentalis Leafy Twig	10 [hp_X] in 1 mL
Trifolium Pratense Flower (UNII: 4JS0838828) (Trifolium Pratense Flower - UNII:4JS0838828)	Trifolium Pratense Flower	10 [hp_X] in 1 mL
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	3 [hp_X] in 1 mL
Arctium Lappa Root (UNII: 597E9B13Z3) (Arctium Lappa Root - UNII:597E9B13Z3)	Arctium Lappa Root	3 [hp_X] in 1 mL
Solidago Virgaurea Flowering Top (UNII: 5405K23S50) (Solidago Virgaurea Flowering Top - UNII:5405K23S50)	Solidago Virgaurea Flowering Top	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:55714-2242-1	29.57 mL in 1 BOTTLE, GLASS		
2	NDC:55714-2242-2	59.14 mL in 1 BOTTLE, GLASS		
3	NDC:55714-2242-0	.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	

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-2242) , API MANUFACTURE(55714-2242)

Revised: 3/2011

Newton Laboratories, Inc.