

**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.*

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**Prostate 4758L**

## **INDICATIONS & USAGE SECTION**

Formulated for associated symptoms such as discomfort, frequent, incomplete or difficult urination.

## **DOSAGE & ADMINISTRATION SECTION**

**Directions:** Adults, take 6 drops by mouth one to four times daily or as directed by a health professional.

## **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, Thyroidinum 15x, Trifolium pratense 15x.

## **OTC - PURPOSE SECTION**

Formulated for associated symptoms such as discomfort, frequent, incomplete or difficult urination.

## **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**

**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**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55714-4758
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>IODINE</b> (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	15 [hp_X] in 1 mL
<b>THYROID, UNSPECIFIED</b> (UNII: 0B4FDL9I6P) (THYROID, UNSPECIFIED - UNII:0B4FDL9I6P)	THYROID, UNSPECIFIED	15 [hp_X] in 1 mL
<b>BARIUM CARBONATE</b> (UNII: 6P69D8HQ8) (BARIUM CATION - UNII:V645272HLN)	BARIUM CARBONATE	15 [hp_X] in 1 mL
<b>BERBERIS VULGARIS ROOT BARK</b> (UNII: 1TH8Q20J0U) (BERBERIS VULGARIS ROOT BARK - UNII:1TH8Q20J0U)	BERBERIS VULGARIS ROOT BARK	15 [hp_X] in 1 mL
<b>BRYONIA ALBA ROOT</b> (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	15 [hp_X] in 1 mL
<b>OYSTER SHELL CALCIUM CARBONATE, CRUDE</b> (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	15 [hp_X] in 1 mL

<b>CINCHONA OFFICINALIS BARK</b> (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB)	CINCHONA OFFICINALIS BARK	15 [hp_X] in 1 mL
<b>CONIUM MACULATUM FLOWERING TOP</b> (UNII: Q28R5GF371) (CONIUM MACULATUM FLOWERING TOP - UNII:Q28R5GF371)	CONIUM MACULATUM FLOWERING TOP	15 [hp_X] in 1 mL
<b>DIGITALIS</b> (UNII: F1T8QT9U8B) (DIGITALIS - UNII:F1T8QT9U8B)	DIGITALIS	15 [hp_X] in 1 mL
<b>FERRIC PICRATE</b> (UNII: KZM8ZRY36A) (FERRIC CATION - UNII:9104LML611)	FERRIC CATION	15 [hp_X] in 1 mL
<b>GOLDENSEAL</b> (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	15 [hp_X] in 1 mL
<b>LYCOPODIUM CLAVATUM SPORE</b> (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	15 [hp_X] in 1 mL
<b>STRYCHNOS NUX-VOMICA SEED</b> (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	15 [hp_X] in 1 mL
<b>CHONDRODENDRON TOMENTOSUM ROOT</b> (UNII: 395A3P448Z) (CHONDRODENDRON TOMENTOSUM ROOT - UNII:395A3P448Z)	CHONDRODENDRON TOMENTOSUM ROOT	15 [hp_X] in 1 mL
<b>ANEMONE PULSATILLA</b> (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	15 [hp_X] in 1 mL
<b>SAW PALMETTO</b> (UNII: J7WWH9M8QS) (SAW PALMETTO - UNII:J7WWH9M8QS)	SAW PALMETTO	15 [hp_X] in 1 mL
<b>SELENIUM</b> (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	15 [hp_X] in 1 mL
<b>DELPHINIUM STAPHISAGRIA SEED</b> (UNII: 00543AP1JV) (DELPHINIUM STAPHISAGRIA SEED - UNII:00543AP1JV)	DELPHINIUM STAPHISAGRIA SEED	15 [hp_X] in 1 mL
<b>THUJA OCCIDENTALIS LEAFY TWIG</b> (UNII: 1NT28V9397) (THUJA OCCIDENTALIS LEAFY TWIG - UNII:1NT28V9397)	THUJA OCCIDENTALIS LEAFY TWIG	15 [hp_X] in 1 mL
<b>TRIFOLIUM PRATENSE FLOWER</b> (UNII: 4JS0838828) (TRIFOLIUM PRATENSE FLOWER - UNII:4JS0838828)	TRIFOLIUM PRATENSE FLOWER	15 [hp_X] in 1 mL
<b>ECHINACEA, UNSPECIFIED</b> (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	6 [hp_X] in 1 mL
<b>ARCTIUM LAPPAL ROOT</b> (UNII: 597E9B3Z3) (ARCTIUM LAPPAL ROOT - UNII:597E9B3Z3)	ARCTIUM LAPPAL ROOT	6 [hp_X] in 1 mL
<b>SOLIDAGO VIRGAUREA FLOWERING TOP</b> (UNII: 5405K23S50) (SOLIDAGO VIRGAUREA FLOWERING TOP - UNII:5405K23S50)	SOLIDAGO VIRGAUREA FLOWERING TOP	6 [hp_X] in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-4758-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/02/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		09/02/2019	

**Labeler** - Newton Laboratories, Inc. (788793610)

**Registrant** - Newton Laboratories, Inc. (788793610)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Newton Laboratories, Inc.		788793610	manufacture(55714-4758)

Revised: 12/2020

Newton Laboratories, Inc.