

**PROSTATE DROPS™**

NPN: 80101752

**1 mL (32 Drops) of Oral Tincture contains:****Saw Palmetto** (333.3 mg DHE\* – *Serenoa repens* fruit)**Bilberry** (212.6 mg DHE\* – *Vaccinium myrtillus* leaf)**Nettle** (165.4 mg DHE\* – *Urtica dioica* leaf)**Juniper** (96.9 mg DHE\* – *Juniperus communis* fruit)**Birch** (48.3 mg DHE\* – *Betula pendula* leaf)**Corn Silk** (48.3 mg DHE\* – *Zea mays* stigma & style)Linden (48.3 mg DHE\* – *Tilia x europaea* flower)**White Willow** (48.3 mg DHE\* – *Salix alba* bark)**Goldenseal** (34.6 mg DHE\* – *Hydrastis canadensis* root)**Uva-ursi** (24.0 mg DHE\* – *Arctostaphylos uva-ursi* leaf)

\*DHE = Dry Herb Equivalent.

**Non-medicinal ingredients:**

purified water, ethanol USP, glycerin, spearmint flavour.

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**Directions of Use:**

Adult males take 1 ml, 3 times daily with food to minimize gastric disturbance. Take a few hours before or after any medication or natural health product. Do not take with high acid foods (e.g. citrus fruits and juice) or medications which may acidify urine. For occasional use only. Consult a health care practitioner for use beyond 1 week.

**Indication:**

Used in Herbal Medicine to help relieve the urological symptoms (e.g. weak urine flow, incomplete voiding, frequent day- and night- time urination) associated with mild to moderate benign prostatic hyperplasia (BPH).

**Detailed Information:**

**Prostate Drops™** is a hydroethanolic tincture containing extracts of ten (10) herb ingredients, mainly saw palmetto fruit, that is licensed as a Natural and Non-prescription Health Product (NNHP) in Canada for use in Herbal Medicine to help relieve urological symptoms associated with mild to moderate benign enlargement of the prostate gland. The combined actions/effects of bilberry leaf, nettle leaf, juniper fruit, birch leaf, linden flower, white willow bark, goldenseal root, and uva ursi leaf help to safely support and complement the action of the saw palmetto fruit in this formulation.

**Saw palmetto fruit** preparations have been Traditionally indicated for cystitis and inflammation and catarrh of the genitourinary tract<sup>1,2</sup>. They are used in Herbal Medicine at a crude equivalent dosage of 1-4 g/day to help relieve the urological symptoms (e.g. weak urine flow, incomplete voiding, frequent day- and night-time urination) associated with mild to moderate BPH<sup>3,4</sup>. While the fruit of saw palmetto contains polysaccharides, flavonoids, triterpenes, and essential oil, they are also a rich source of free fatty acids, as well as of sterols, especially  $\beta$ -sitosterol<sup>4</sup>. Inasmuch, the majority of saw palmetto fruit preparations have focussed on lipido-sterolic extracts and their constituents, especially those obtained using hexane, 90% ethanol, and CO<sub>2</sub><sup>5</sup>. A relatively large number of placebo-controlled clinical studies have been carried out using these extracts, which have demonstrated relief of urological symptoms in patients with mild to moderate BPH<sup>4,5</sup>. It is on the basis of saw palmetto fruit and its active constituents that the **Prostate Drops™** formulation is primarily based, with complementary support provided by the other herb extract ingredients.

**Bilberry leaf** preparations have a long history of folk and Traditional use by North American Indians and by people in Europe for, among other things, kidney and urinary tract disorders, gout, poor circulation, functional heart problems, and for “metabolic stimulation and blood purification”<sup>2,6-9</sup>. In TCM, bilberry leaf is used for venous insufficiency and capillary fragility, as well as atherosclerosis and hypertension<sup>7</sup>. Animal studies support its vasoprotective and anti-edema properties<sup>8</sup>. Active constituents of bilberry leaf preparations are considered to include polyphenols, tannins, flavonoids (e.g. avicularin, quercetin, hyperoside), as well as manganese and chromium<sup>9</sup>. The herb’s astringent, anti-inflammatory, and urinary antiseptic properties complement the **Prostate Drops™** formulation; and its circulatory stimulant properties help in the removal of toxic and waste substances, and provide support for genito-urinary system health in general.

**Nettle leaf** preparations are Traditionally used in Herbal Medicine for, among other things, their diuretic and nutritive tonic effects<sup>4,8-10</sup>. The German Commission E approved the internal use of nettle herb/leaf as irrigation therapy for inflammatory diseases of the lower urinary tract and prevention and treatment of kidney gravel. The German Standard License for nettle herb tea indicates its use for increasing the amount of urine and for treating urinary complaints<sup>2,9,12</sup>. Its ability to help decrease inflammation and assist eliminative function<sup>13</sup> makes it an important complementary ingredient of the **Prostate Drops™** formulation.

**Juniper fruit** preparations have a long history of use as a general diuretic and soothing kidney remedy<sup>14</sup>, and are considered to be specific for cystitis when renal inflammation is absent<sup>1</sup>. They are Traditionally useful in all cases of renal congestion, aching through the back and loins, bladder catarrh, etc., and have a distinct tonic effect on tissues of the genitourinary tract<sup>15</sup>. Juniper is Traditionally used in Herbal Medicine as a diuretic and urinary antiseptic to help relieve benign urinary tract infections<sup>16</sup>, although it is principally used as an adjunct with other diuretics<sup>17</sup>. Its use in combination with other herbs/botanicals is considered to be helpful in the treatment of all prostate (and kidney) problems<sup>2</sup>.

**Birch leaf** is also used in Herbal Medicine as a diuretic<sup>18</sup>. It is indicated for irrigation of the urinary tract, especially in cases of inflammation and renal gravel, and as an adjuvant in the treatment of bacterial infections and spasmodic disorders of the urinary tract<sup>4,5,8,9,11</sup>. Its mild diuretic, anti-inflammatory, antiseptic and tonic actions have made the herb a useful and common component of diuretic/urological combination products<sup>9</sup>.

**Corn Silk.** Due to its diuretic, urinary demulcent, anti-inflammatory, antilithic, antiseptic, and tonic effects, corn silk is Traditionally indicated in all catarrhal and inflammatory conditions of the urinary system, dysuria, cystitis, and prostatitis<sup>1,8,9,12,14</sup>. It has been described as the archetypal urinary demulcent, helpful for any urinary irritation". It is commonly included as an ingredient of combination products "because of the wide range of urinary disorders it addresses and because of its reliable action"<sup>7</sup>.

**The Linden Flower** has been Traditionally described as, among other things, stimulant, tonic, antispasmodic, anti-inflammatory, and astringent in its actions<sup>2,9,11,12,17</sup>. It is also Traditionally considered to be diuretic<sup>1,9,19</sup>. These combined effects support its common use as a supportive and complementary ingredient in multi-ingredient urological formulations<sup>2</sup> like **Prostate Drops™**.

Health Canada acknowledges the Traditional use of **White Willow Bark** in Herbal Medicine for relief of low back, headache, and minor joint pain, and of fever associated with the common cold<sup>20</sup>. These indications can be attributed to the herb's recognized tonic, anodyne, anti-inflammatory, astringent, and diaphoretic properties<sup>1,2,11,12,14,15,17</sup>. However, white willow bark is also Traditionally known to be diuretic<sup>2,12,14</sup>. It is indicated in all r

cases where pain is caused by inflammation<sup>9</sup>. Its multiple actions are, therefore, supportive and to those of the other herbs in the **Prostate Drops™** formulation.

The multiple actions of **Goldenseal Root**, including antiseptic, antimicrobial, anti-catarrhal, astringent, and diuretic<sup>1,12,13,14,17,21</sup>, make it one of the most useful and powerful of all Traditional herbal remedies<sup>22,23,24</sup>. The herb is specifically indicated as an anti-inflammatory and tonic or inflammations of mucous membranes<sup>1,12,13,21,23</sup>. It is commonly used today to help in the management of infectious and inflammatory conditions of the genitourinary system, including for catarrh of the bladder<sup>25,26</sup>.

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The leaf of **Uva-ursi** is specifically indicated for Traditional use in Herbal Medicine for bladder and kidney diseases, helping to soothe, strengthen and tonify the urinary passages and reduce inflammation of the urinary tract<sup>11,13,15,17</sup>. It has been considered one of the most effective herbal antiseptics for urinary tract infections and cystitis since the Middle Ages<sup>11,13</sup>. It has also been used in folk and Native American medicines as a diuretic for congested kidneys, and as a urinary aid and tonic for bladder and kidneys<sup>1,2,27,28,29</sup>, especially in small doses<sup>17</sup>. Its beneficial use in cases of urinary incontinence, aching kidneys and bladder, and congestion and ulceration of the bladder and prostate gland, have been known for over 150 years<sup>15</sup>. Like many of the other herbs in the **Prostate Drops™** formulation, Uva-ursi leaf preparations are Traditionally used in Herbal Medicine as a mild diuretic, and to help relieve symptoms associated with minor urinary tract infections<sup>30</sup>.

The specific combination of herbal extract ingredients making up the **Prostate Drops™** formulation is unique, and provides a safe, gentle and effective product for its licensed use as a NNHP to help relieve the urological symptoms associated with mild to moderate BPH when taken as recommended.

**Cautions and Warnings:**

Consult a health care practitioner if symptoms persist or worsen. Consult a health care practitioner prior to use to exclude the diagnosis of prostate cancer; if you have asthma or peptic ulcer disease, swelling due to a kidney or cardiovascular disorder, blood pressure problems, or a liver disorder, fever, painful urination (dysuria), spasms, or blood in urine; or are taking anticoagulants or products containing ASA or other salicylates. Discontinue use and consult a health care practitioner if you experience gastrointestinal symptoms such as nausea, vomiting, abdominal pain, dyspepsia, heartburn or diarrhea.

**Contra-Indications:**

Avoid taking with alcohol, other medications and /or natural health products with sedative properties. Do not take if you have a kidney disorder or diabetes, or are allergic to acetylsalicylic acid (ASA) or other salicylates.

**Known Adverse Reactions:**

Allergy is known to occur, in which case discontinue use.

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