

Prostate Formula Softgels

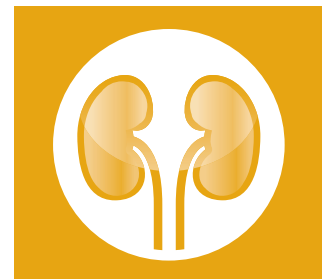


Product Summary:

Benign prostatic hyperplasia (BPH) is a very common and uncomfortable problem in older men. diem's Prostate Formula contains saw palmetto extract, pygeum bark and other vegetable extracts to help relieve urological symptoms associated with mild to moderate BPH.

Properties/Uses:

The claim as approved by the *Natural Health Products Directorate* (NHPD): Used in herbal medicine to help relieve the urologic symptoms (e.g., weak urine flow, incomplete voiding, frequent daytime and night time urination) associated with mild to moderate benign prostatic hyperplasia.



URINARY



Pharmacology:

Benign prostatic hyperplasia (BPH) is a very common and uncomfortable problem in older men. Symptoms are caused by cell proliferation resulting in an enlarged prostate. This in turn puts pressure on the urethra, causing urinary symptoms such as weak urine flow, incomplete voiding, frequent daytime and nighttime urination. Over half of men over age 60 have some prostate enlargement.

The use of plant extracts for treatment of lower urinary tract symptoms consistent with BPH was first described in Egypt in the 15th century BCE.¹ This prostate formula includes saw palmetto extract, pygeum bark, pumpkin seed oil and organic flaxseed oil.

Saw palmetto extract is isolated from small palm tree (*Serenoa repens*) berries. It is a traditional herbal remedy used to reduce prostate gland enlargement by inhibiting dihydrotestosterone (DHT) generation and expression. DHT is a metabolite of testosterone that increases cell proliferation and glandular size. Saw palmetto is believed to function in much the same way as reductase inhibitors such as finasteride and dutasteride.

Clinical studies into saw palmetto extract's effectiveness show it may be more effective at relieving BPH symptoms than the prescribed drug Proscar (finasteride). It has been shown to improve symptoms such as urination frequency, pain, hesitation and urgency. In one study, saw palmetto extract was effective in nearly 90% of patients after 4-6 weeks, while Proscar was effective in less than 50% of patients after one year. It also has more tolerability than Proscar.²

Pygeum africanum, African plum tree, has been used traditionally in African folk herbal medicine for male urinary problems of BPH and acts similarly to saw palmetto. Pygeum has also been well-studied for BPH symptoms and has enjoyed clinical success. Used in combination, pygeum africanum can complement saw palmetto in cases where it has failed to make significant improvements in the symptoms of BPH.

Pygeum africanum has been used to treat BPH symptoms due to its antiproliferative and anti-inflammatory effects. Studies have shown that pygeum effectively reduces the functional symptoms of BPH.³ Pygeum decreases nocturia by 19%, increases peak urine flow by 23%, and reduces residual urine volume by 24% in men with BPH.⁴ Preclinical research suggests that pygeum improves bladder contractility.

Pygeum also produces a cholesterol lowering effect in the prostate gland. Accumulation of cholesterol break-down metabolites are associated with BPH and prostate cancer, a condition that leads to even greater hyperplasia.² Drugs that lower cholesterol systemically, can exert a beneficial effect on BPH.



Pumpkin seed oil (*Cucurbita pepo*), which is rich in carotenoids, is included for additive benefit with saw palmetto extract.⁵ Flaxseed oil is a rich source of fatty acids, particularly alpha-linoleic acid (ALA) and omega-3 fatty acids. It is included for its cholesterol-lowering and anti-inflammatory benefit.

Note: Prostate enlargement should be co-treated with zinc, since zinc depletion is a primary risk factor for benign prostatic hyperplasia.





Manufactured product information :

Manufacturer:

WN Pharmaceuticals® Ltd.

Size/UPC:

60's 7 77747 10268 6

NPN:

80011069

Expiry Date:

42 months from date of manufacture

Active Ingredients:

Each softgel contains :

Saw Palmetto (<i>Serenoa repens</i>) (fruit) (85 – 95% free fatty acids, esters and sterols) . . .	80 mg
Pygeum (<i>Prunus africana</i>) (bark) (13% sterols)	20 mg
Pumpkin Oil (<i>Cucurbita pepo</i>) (seed)	130 mg
Organic Flaxseed Oil (<i>Linum usitatissimum</i>) (seed)	130 mg

Non-Medicinal Ingredients (in descending order):

Softgel capsule (gelatin, glycerin, purified water, carob), lecithin, yellow beeswax.

Appearance:

Amber coloured oil encapsulated in an oblong brown coloured soft gelatin shell.

Packaging:

175 cc white round bottle with safety seal under a 38 mm white induction sealed cap with vented interior seal and a label applied to the bottle. Lot number and expiry date are printed on label applied to exterior of bottle.

Storage:

Preserve in tight, light resistant containers.





Dose:

According to the NHPD for adult males, the appropriate dose of saw palmetto fruit extract is 320 mg per day.⁶

In BPH clinical trials, doses of 75-200mg/day of pygeum bark have been used.⁷

For BPH, doses of 160 mg of pumpkin seed oil TID has been used with other herbs.⁸

For BPH, one tablespoon of flaxseed oil is recommended.⁹

Directions:

(Adults): 3 softgels daily, with food to minimize gastric disturbance, or as recommended by a physician. Consult a physician for use beyond 12 months.

Caution:

The caution as approved by the *Natural Health Products Directorate* (NHPD): KEEP OUT OF THE REACH OF CHILDREN. Consult a physician before use to exclude a diagnosis of prostate cancer. Consult a physician if symptoms persist or worsen. Discontinue use if gastrointestinal upset occurs. Not intended for use by women. STORE AT ROOM TEMPERATURE IN A DARK, DRY PLACE. DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.

Deficiency Symptoms:

N/A

Drug Interactions/Contraindications:

Saw palmetto might have antiestrogenic effects and may interfere with contraceptive drugs and hormone therapy.¹⁰

Anticoagulant/antiplatelet herbs/drugs: Saw palmetto and flaxseed oil might increase the risk of bleeding when used concomitantly with these drugs.^{9,10}

Surgery: Discontinue use 2 weeks prior to elective surgery.^{9,10}



Toxicity/Adverse Reactions:

The adverse effects of saw palmetto are generally mild but may include dizziness, headaches and gastrointestinal complaints. In one case, a patient developed acute hepatitis and pancreatitis while taking saw palmetto.¹⁰ Orally, pygeum bark is generally well tolerated; however, it can cause nausea and abdominal pain.⁴ Pumpkin is thought to have diuretic properties.⁸ Flaxseed oil is well-tolerated; however, this dosage has been associated with loose stools and diarrhea.⁹





Allergen Content/Ingredient Sensitivity:

NO	YES
Artificial Colors	Lecithin
Artificial Flavors	Sulphites (<10 ppm)
Artificial Sweeteners	
Corn Products	
Egg Products	
Fish	
Gluten	
Hydrolyzed Plant Protein	
Milk Products	
Peanuts	
Preservatives	
Sesame Products	
Shellfish	
Soy Products	
Starch/Modified Starch	
Tartrazine	
Tree Nuts	
Wheat Products	
Yeast	

NOT ACCEPTABLE FOR THE FOLLOWING DIETARY RESTRICTIONS:

Free of Animal Products

Kosher





References:

1. Lowe FC, Ku JC. Phytotherapy in treatment of benign prostatic hyperplasia: a critical review. *Urology* 1996; 48:12-20.
2. Murray, MT *The Healing Power of Herbs*, Prima Publishing, Rocklin, CA, 1992
3. Murray, Michael, *The Pill Book Guide to Natural Medicines*, Bantam, Toronto, 2002
4. Natural Medicine Comprehensive Database, Pygeum Monograph, Accessed October 2010 [Available from: <http://www.naturaldatabase.com/>]
5. Wilt TJ, Ishani A, Rutks I, MacDonald R. Phytotherapy for benign prostatic hyperplasia. *Public Health Nutr.* 2000; 5(4A):459-472.
6. Health Canada, Saw Palmetto Monograph, Accessed September 2009. [Available from: <http://www.hc-sc.gc.ca>]
7. Ishani A, MacDonald R, Nelson D, Rutks I, Wilt TJ. Pygeum africanum for the treatment of patients with benign prostatic hyperplasia: a systematic review and quantitative meta-analysis. *Am J Med.* 2000 Dec 1; 109(8):654-664.
8. Natural Medicine Comprehensive Database, Pumpkin Monograph, Accessed September 2009 [Available from: <http://www.naturaldatabase.com/>]
9. Natural Medicine Comprehensive Database, Flaxseed Oil Monograph, Accessed October 2010 [Available from: <http://www.naturaldatabase.com/>]
10. Natural Medicine Comprehensive Database, Saw Palmetto Monograph, Accessed September 2009 [Available from: <http://www.naturaldatabase.com/>]

Revision # 00