COLLEEN MAY

Flower Pollen Extract and its ability to reduce symptoms of benign prostate hyperplasia (BPH)

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WHAT IS BPH?

Benign prostate hyperplasia (BPH) is a condition that causes an increase in the size of the prostate gland in aging men. The prostate gland is divided into many different lobes which function together to generate and expel prostatic fluid. The transitional zone, located inside of the prostate's middle lobe, is the area in which BPH is thought to occur. BPH is characterized by hyperplasia, or the abnormal proliferation of cells in the prostatic stromal and epithelial cells, which results in the formation of large nodules inside the prostate.

Even though the prostate serves no direct function in the male urinary system, its location near the urethra causes some interactions to occur. Once the prostate gland begins to swell, the urethral canal, which runs through the middle lobe, becomes either partially or completely obstructed, causing BPH symptoms. Symptoms of BPH include low urinary frequency, urinary urgency, urgency incontinence, nocturia (voiding at night), weak urinary stream, stream hesitancy, stream intermittency, straining to void and sensation of incomplete voiding. If not treated, over time BPH can block or squeeze the urethral canal completely closed, which leads to other urinary tract problems that may damage the kidneys.

BPH becomes more common with advancing age, with up to 80% of men at the age of 90 experiencing a certain degree of BPH symptoms. Treatment for BPH ranges from careful monitoring to invasive surgery. Mild cases of BPH are often times monitored without prescription drug treatment. More severe cases are now being treated non-invasively with various laser treatments. Despite the new advances in treatment options for BPH, men with mild to moderate cases are often told to wait

until the condition worsens to begin a prescription drug treatment. This is where dietary supplement products become

WHAT IS FLOWER POLLEN EXTRACT?

Flower Pollen Extract is a standardized extract from flower pollen that has been used historically for over 50 years to support prostate health. This product is supported by a substantial amount of open, placebo-controlled and doubleblind clinical trials. Flower Pollen Extract has been given to men for prostate health with peace of mind and without harmful side effects as an alternative to pharmaceuticals for many BPH patients (1). Flower Pollen Extract is produced using a combination of unique growing and processing techniques. A specific number of selected plants contribute their pollen to produce Flower Pollen Extracts. These plants are chosen after acute dermal, oral and genetic toxicity assay are completed. The different pollens are harvested mechanically from the fields and are further processed to remove any plant material to isolate the pure pollen.

Once in pure form, the pollen is extracted to remove the outer shell and release the internal nutrients. This extraction process is now being done without the use of solvents by Graminex[®]. During the extraction process the outer shells of the pollen grains along with the allergens are discarded, leaving only the nutrients inside of the pollen grains behind. Through this process substances that are toxic or harmful, like allergens and other high-molecular substances, are broken down and eliminated. This allows Flower Pollen Extracts to be safely used by people who are otherwise allergic or hypersensitive to

other pollen products.

During the manufacturing process the Flower Pollen Extract is separated into two portions, a lipid soluble portion and a water soluble portion. The lipid soluble portion contains the phytosterols while the water soluble portion contains the amino acids. These two portions are then blended together to form a standardized Flower Pollen Extract. It is the synergistic effect of the combination of lipid and water soluble nutrients that makes Flower Pollen Extract unique. Graminex Flower Pollen Extract™ is a standardized product that meets the exact specifications for phytosterol and amino acid content for every batch.

Table I – Chemical composition of Graminex G63™ Flower Pollen Extract

Extract						
	Vitamins	Minerals	Amino Acids			
L.	Provitamin A (carotenoids)	Calcium	Alanine			
	B1 Thiamine	Phosphorus	Alpha-amino butyric acid			
	B2 Riboflavin	Potassium	Arginine			
	Niacin	Sulphur	Asparagine			
Н	B6 Pyridoxine	Sodium	Aspartic acid			
	Pantothenic acid	Clorine	Cysteine			
	Biotin	Magnesium	Cystine			
	B 12 (Cyanocobalamirn)	Iron	Glutamic acid			
	Folic Acid	Manganese	Glutamine			
	Choline	Copper	Glycine			
	Inositol	lodine	Histidine			
	Vitamin C	Zinc	Hydroxyproline			
	Vitamin D	Silicon	Isoleucine			
)	Vitamin E	Chromium	Leucine			
	Vitamin K	Molybdenum	Lysine			
	Ratin	Boron	Methionine			
	F A	Titanium	Phenylalanine			
	Fatty Acids	5	Proline			
	Caprylic acid (C-8)	Polar Lipids	Serine			
E.	Capric (C-10)	Lecithin	Taurine			
	Lauric (C-12)	Lysolecithin	Threonine			
	Myristic (C-14)	Phosphoinositol	Tryptophan			
	Myristoleic (C-14)	Phosphatidylcholine	Tyrosine Valine			
	Pentadecanoic (C-15)	Navitaal Linida	Valine			
	Palmitic (C-16)	Neutral Lipids	Flavoraida			
	Palmitoleic (C-16)	Monoglycerides	Flavanoids Quercetin			
	Heptadecanoic (C-17) Stearic (C-18)	Diglycerides Triglycerides	Dihydroxquercetin			
	Oleic (C-18)	Free fatty acids	Naringenin			
	Linoleic (C-18)	Sterols	P-coumaric acid			
i.	Linolenic (C-18)	Hydrocarbons	Apigenin			
	Arachidic (C-20)	Trydrocarbons	Sorhamnetin			
f	Eicosenoic (C-20)	Phytosterols	Myricetin			
	Eicosadienoic (C-20)	Fucosterol	Isorhemnetin			
	Eicosatrienoic (C-20)	Beta-sitosterol	Kaempferol			
	Arachidonic (C-20)	Stigmasterol	Dihydrokaempferol			
	/ "dollidollio (0-20)	Cholesterol	Luteolin			
t		Campesterol				
		Estrone				
			l			

bound arachidonic acid (2). The biosynthesis of these inflammatory mediators is initiated by two enzymes: cyclo-oxygenase and 5-lipoxygenase. The activities of both the cyclo-oxygenase and 5-lipoxygenase enzymes are markedly reduced as well as the overall quantity of arachidonic acid with Flower Pollen Extract treatment (Figure 2). The inhibition of the arachidonic acid cascade by Flower Pollen Extract helps prevent intraprostatic tissue edema from occurring in the prostate's middle lobe as well as fibrosis. In stage II and stage III BPH patients, studies show the anti-congestive effect of Flower Pollen Extract leads to a marked

arachidonic acid cascade (Figure 1). The

majority of known mediators that cause

inflammation come from the membrane-

In stage II and stage III BPH patients, studies show the anti-congestive effect of Flower Pollen Extract leads to a marked reduction in prostate volume (3). A transrectal ultra sonogram of the prostate before and after six months of treatment with Flower Pollen Extract clearly shows the marked reduction of the circumference, transverse and a-p diameter of the prostate (Figure 3). By reducing this internal swelling and fibrosis, there is a significant reduction in the clinical symptoms associated with RPH

In BPH patients the anti-congestive effect of Flower Pollen Extract leads to a lasting improvement of urinary voiding difficulties. High improvement rates are also obtained in one of the main symptoms of BPH, namely nocturia. The residual urine volume decreases significantly, on average by 47% (4). In a double blind study the superiority of Flower Pollen Extract from Graminex® in comparison with a placebo was found to be significant (Table II). This study shows significant differences in favor of Flower

Chemical Composition of Flower Pollen Extract

The pollen grains used to manufacture Flower Pollen Extract contain the complete profile of nutrients vital for human health. Many of these nutrients are beneficial to improving prostate health. Included in the chemical composition are a variety of vitamins, carotenoids, minerals, amino acids, enzymes, lipids, fatty acids, prostaglandins, phytosterols, hydrocarbons and flavanoids (Table I). These substances are present naturally in the Flower Pollen Extract and act synergistically inside the prostate gland to help alleviate BPH symptoms and improve prostate health.

MECHANISM OF ACTION OF FLOWER POLLEN EXTRACT AND ITS EFFECTS

Anti-Congestive and Anti-Inflammatory

Inflammation of the prostate results in edema, or the abnormal accumulation of

fluid in the interstitial stromal tissue surrounding the acini and ducts of the

gland, leading to congestion and poor secretory drainage. The swelling of the prostate gland that occurs as a result of this process can affect the normal and the hyperplasic gland, causing difficulties with voiding, dysuria, frequency and nocturia. This swelling accounts for the discomfort and pain that occurs as a result of chronic non-bacterial prostatitis and prostatodynia.

The anti-congestive action of Flower Pollen Extract is based on the inhibition of the prostaglandin and leukotriene biosynthesis during the

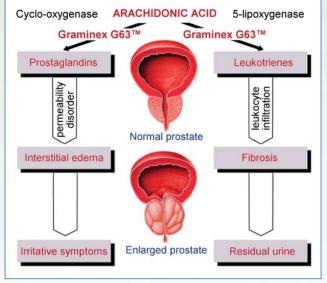
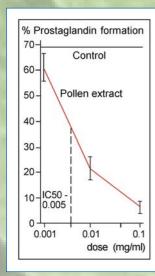


Figure 1 – Graminex G63™ Flower Pollen Extract inhibits the cyclo-oxygenase and the 5-lipoxygenase and thus reduces the biosynthesis of prostaglandins and leukotrienes from arachidonic acid (2)



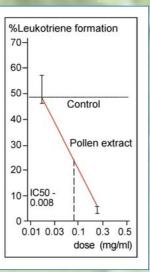


Figure 2 – Reduction in the biosynthesis of prostaglandins and leukotrienes after treatment with Flower Pollen Extract

active controlled and open-label studies, Flower Pollen Extract is considered a safe and effective therapy for the management of mild to moderate lower urinary tract symptoms caused by BPH and other prostate problems (12,13). Acute oral and acute dermal toxicity studies and genetic toxicology assay, including LD₅₀ have been completed for one Flower Pollen Extract preparation, Graminex G63™, showing that is non-toxic and considered safe.

Pollen Extract in both clinical symptomatology and urodynamics (5). In another study conducted using Graminex G63™ Flower Pollen Extract, patients experienced an improving trend in their symptoms of perineal pain, erection, ejaculation difficulty and pain during urination (1). Similar studies have also shown an improvement in chronic prostatitis and prostatodynia (6,7). One study conducted in

patients with

prostatodynia using Graminex

Flower Pollen

a marked

Extract™ showed

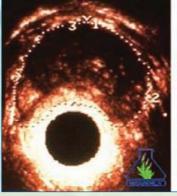
improvement of

the associated

symptoms (8).

On average the study showed 78% of patients showed an improvement in symptoms and 60% showed a complete cure (Table III). In the majority of patients there was either complete or lasting relief of symptoms. Numerous placebo-controlled, double blind studies with Flower Pollen Extract provide evidence that it is effective in reducing nocturnia, daytime frequency and sensation of residual urine (4,9-11).

After reviewing placebo-controlled trials,



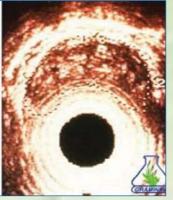


Figure 3 – Transrectal ultra sonography of the prostate before and after six months treatment with Flower Pollen Extract (4)

Table II – Results of a double-blind study: Significant differences in favor of Flower Pollen Extract in clinical symptomology and urodynamics (5)

Parameter	Active Drug	Placebo	Significance P value
Clinical symptom	Response (%)		
Nocturia	66.7	37.2	0.011
Frequency	6.9	37.0	0.023
	Symptom-free (%)		
Frequency	45.2	15.2	0.003
Sensation of incomplete emptying	38.2	3.8	0.005
Urodynamics Residual urine		Volume	
- before therapy (ml: x ± s)	54.5 ± 24.9	51.9 ± 32.0	
- after therapy (ml: x ± s)	28.9 ± 19.7	44.9 ± 28.6	0.001
- reduction (%)	47.0	13.5	

Table III – Marked improvement of the symptoms in prostatodynia due to Flower Pollen Extract (8)

Symptom	Symptom-free	Improved
Pain	52.4 %	76.2 %
Dysuria	60.0 %	76.7 %
Nocturia	57.1 %	92.9 %
Frequency	63.3 %	63.3 %
Discomfort	61.5 %	80.8 %

CONCLUSION

Flower Pollen Extract is an interesting ingredient in the nutraceutical and pharmaceutical industry for the treatment of BPH symptoms. As a natural botanical extract, Flower Pollen Extract may be used in combination with other dietary supplements and pharmaceuticals to provide relief for men experiencing bothersome BPH symptoms.

The unique growing, manufacturing process and exact standardization methods provide a Flower Pollen Extract that goes beyond and is superior to the normal botanical extracts and bee pollen on the market. The chemical makeup of each batch of Graminex Flower Pollen Extract™ is the same each and every time it is manufactured, so finished goods contain the same levels of nutrients every time

In addition to the quality standards, there exists a substantial amount of clinical trial data to support Flower Pollen Extract's use for men's prostate health, specifically to reduce symptoms associated with BPH. Primary and secondary scientific literature provides sufficient evidence that Flower Pollen Extract is safe and effective for the treatment of BPH symptoms. Men who suffer from mild to moderate symptoms of BPH may find Flower Pollen Extract useful to improve their quality of life.

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