



IDEACTIFS®

Active ingredients for functional ideas



GRAMINEX®

Flower Pollen Extracts



Our partner

- Graminex[®] is a family-owned company established in 1997
- 2800 ha of rye farmland in Ohio
- Sustainable agricultural practices
- World's exclusive grower, harvester and producer of standardized flower pollen extracts.
- GMP certified processing plant





Graminex® Flower Pollen Extracts

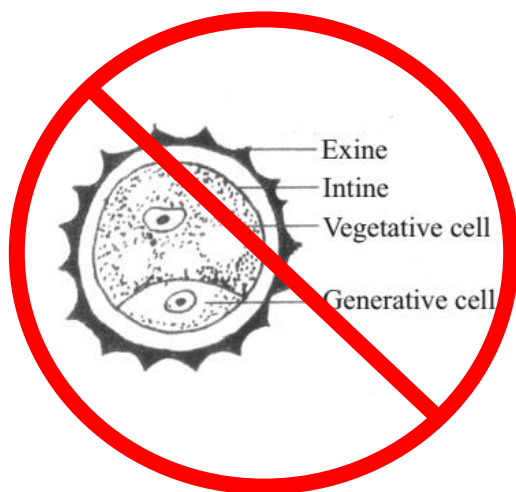
- Allergenic outer shell removed
- Extraction of the cytoplasmic portion of the pollen grain
- H₂O and CO₂ extraction process
- Water & lipid extracts for women's and men's health





Graminex® Flower Pollen Extracts

ALLERGEN-FREE



BEE-FREE



SOLVENT-FREE





Graminex® references

- Graminex® G63® : water and lipid extracts standardized in amino acids and phytosterols (powder)
 - Prostate health : 250 mg/day
 - Chronic prostatitis pelvic pain : 1 g/day
- Graminex® RCT Fem™ Meno : water extract standardized in amino acids (powder)
 - Menopause, Premenstrual syndrome : 300 mg/day
- Graminex® RCT Fem™ UI : lipid extract standardized in phytosterols
 - Urinary incontinence : 18 mg/day (oily paste)
72 mg/day (powder)



Science

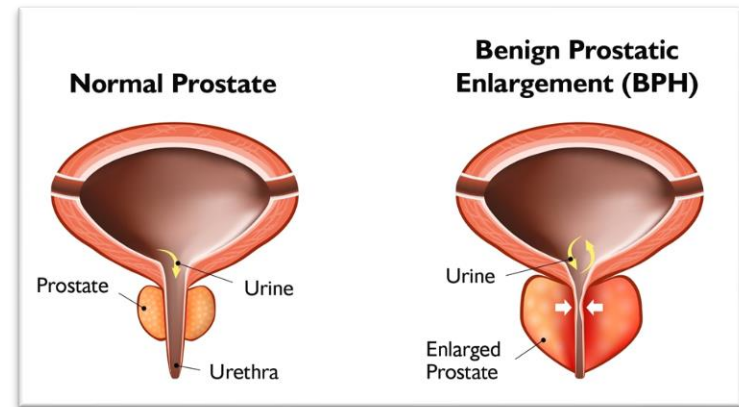


Men's health



Prostate health : urinary symptoms

- Incomplete emptying
- Frequency
- Intermittency
- Urgency
- Weak stream
- Straining
- Nocturia





Flower Pollen extracts : mode of action

- Anti-inflammatory
 - COX/5-LOX inhibition
 - Interleukin reduction (IL6 & IL8)
- Hormonal
 - 5 α -reductase down-regulation
- Antioxidant
 - SOD activity

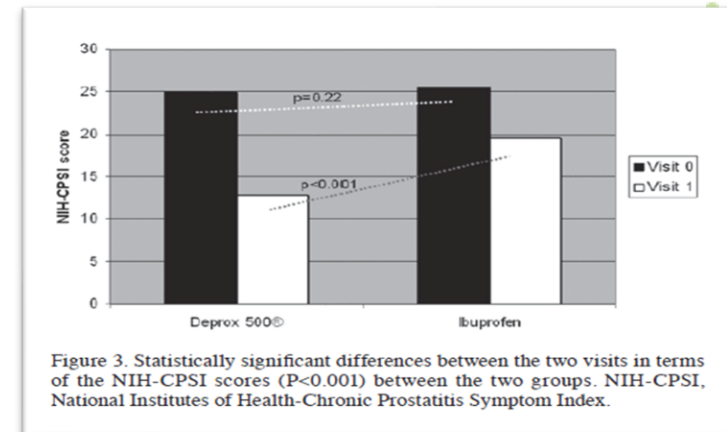


Men's health : study 1

Pollen extract in association with vitamins provides early pain relief in patients affected by chronic prostatitis/chronic pelvic pain syndrome

Cai et al., Experimental and Therapeutic Medicine, 2014

- Size : 80 men (2 groups)
- Daily dosage : 1 g Graminex® G63® (2 caps of Deprox 500) vs 600 mg Ibuprofen
- Duration : 4 weeks
- Results : the pollen extract treatment significantly improves total symptoms, pain and quality of life compared with Ibuprofen in patients with CP/CPPS, without severe side-effects





Men's health : study 2

Flower Pollen Extract in Association with Vitamins (Deprox 500) versus Serenoa repens in Chronic Prostatitis/Chronic Pelvic Pain Syndrome: A Comparative Analysis of Two Different Treatments

Macchione et al., Anti-Inflammatory & Anti-Allergy Agents in Medicinal Chemistry, 2019

- Size : 63 men
- Daily dosage : 1 g Graminex® G63® vs 320 mg Saw Palmetto
- Duration : 6 weeks
- Results : pollen extract significantly more effective than Saw Palmetto

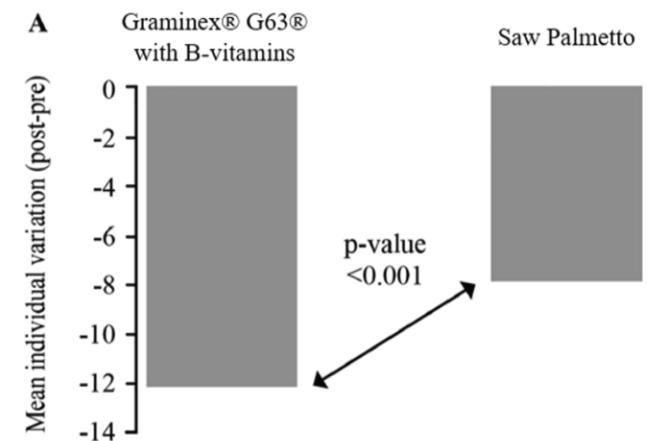


Fig. (4). IPSS score variation (A)
– 6 weeks duration



Men's health : study 3

Treatment of Outflow Tract Obstruction due to Benign Prostatic Hyperplasia with the Pollen Extract, Cernilton

Buck et al., British Journal of Urology, 1990

- Size : 53 men (29 treatment, 24 placebo)
- Daily dosage : 1 g pollen extract
- Duration : 6 months
- Results : the pollen extract has a beneficial effect in Benign Prostatic Hyperplasia and may have a place in the treatment of patients with mild or moderate symptoms of outflow obstruction

Table 1 Frequency of Symptom-free Findings following Cernilton and Placebo at 6 Months

Symptom	Response Rate (%)		P value
	Cernilton	Placebo	
Frequency	37	47	0.664
Daytime	60	30.4	0.063*
Nocturia	47	29	0.480
Hesitancy	71	45	0.157
Urgency	52	33	0.505
Intermittency	57	10	0.004*
Incomplete emptying	61	56	0.99
Terminal dribble	62	71	1.0
Dysuria			

* Statistically significant.



Men's health : study 4

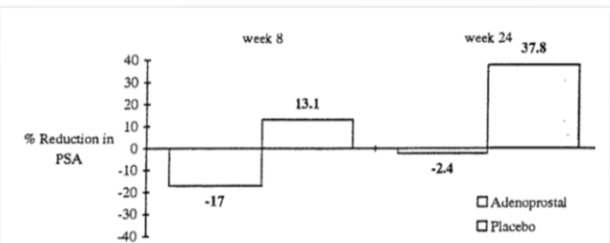
A multicenter, Placebo-controlled Study on the Efficacy and Tolerability of Adenoprostal in Patients with Benign Prostatic Hyperplasia (BHP)

Braun et al., Tribuna Medica Ticinese, 1993

- Size : 44 men (25 treatment, 19 placebo)
- Daily dosage : 750 mg pollen extract
- Duration : 6 months
- Results :
 - reduced volume of the prostate
 - reduced PSA (Prostate Specific Antigen).
 - reduced the number of nocturnal and diurnal micturitions

Table 3. Volume of the prostate (ML)

Treatments	t = 0 weeks	t = 24 weeks
ADENOPROSTAL (N = 21)	44.61 ± 23.25	31.66 ± 14.63 * (-29%)
PLACEBO (N = 17)	46.63 ± 42.50	42.50 ± 20.87 * (-8.8%)





Men's health : study 5

Effects of pollen extract preparation prostat/poltit on lower urinary tract symptoms in patients with chronic non bacterial prostatitis/chronic pelvic pain syndrome

Elist et al., Urology, 2006

- Size : 58 men (30 treatment, 28 placebo)
- Daily dosage : 750 mg pollen extract
- Duration : 6 months
- Results : sexual function significantly better in the patients taking pollen extract after 6 months of treatment

TABLE II. Sexual dysfunction				
Symptom	Dysfunction at Start of Treatment		Dysfunction After 6 mo	
	Prostat/Poltit	Placebo	Prostat/Poltit	Placebo
Sexual dysfunction				
No.	36	44	7	36
Mean \pm SD	1.2 \pm 0.9	1.6 \pm 0.9	0.2 \pm 0.5	1.3 \pm 1.1
Decreased libido (n)	4	8	1	7
Erectile dysfunction (n)	10	14	3	13
Premature ejaculation (n)	14	18	3	13
Delayed ejaculation (n)	8	4	0	3



Men's health : study 6

A pollen extract (Cernilton) in Patients with Inflammatory Chronic Prostatitis-Chronic Pelvic Pain Syndrome: a Multicentre, Randomized, Prospective, Double-Blind, Placebo-Controlled Phase 3 Study

Wagenlehner et al., European Urology, 2009

- Size : 111 men (51 treatment, 60 placebo)
- Daily dosage : 1,5 g pollen extract
- Duration : 12 weeks
- Results : compared to placebo, the pollen extract significantly improves total symptoms, pain, and quality of life in patients with inflammatory CP/CPPS without severe side-effects

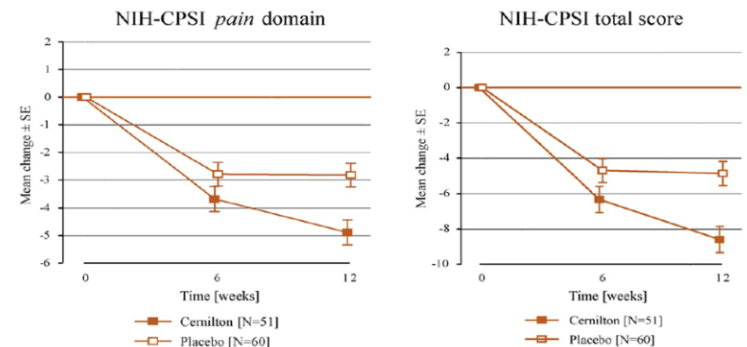


Fig. 2 – Mean change (plus or minus standard error [SE]) from baseline in the National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI) pain domain and in the NIH-CPSI total score after 6 and 12 wk of treatment with pollen extract (Cernilton group) or placebo (per-protocol group).



Men's health : study 7

Clinical evaluation of Cernilton on benign prostatic hypertrophy *Hayashi et al., Kyoto University, 1986*

- Size : 20 men
- Daily dosage : 1,5 g pollen extract
- Duration : 12 weeks
- Results : night frequency, residual and tidal urine volume were improved significantly

Table 4. Changes in numerical values (cases with before and after values, average 13.2 weeks)

Project	Case Number	Before Administration	After Administration	t-test
		M+/-SD	M+/-SD	
Number of urination at night (return)	20	3.1+/-1.4	1.6+/-1.1	p<0.001 (t=6.44921)
Residual urine volume (ml)	14	51.1+/-57.2	16.0+/-22.6	p<0.05 (t=2.35236)
Urine Output (ml)	13	198.7+/-154.2	283.6+/-167.1	p<0.05 (t=2.34810)



Women's health



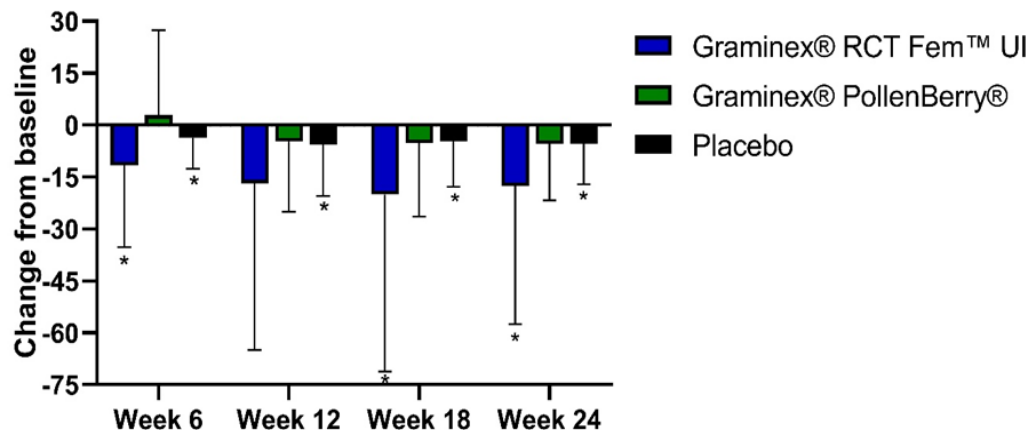
Urinary incontinence



Urinary incontinence: study 1

Efficacy of nonsolvent flower pollen extracts in healthy women with urinary incontinence: A randomized, double-blind, placebo-controlled, parallel study
Moulin et al., Current Urology, 2024

- Size : 114 women (average age: 56)
- Treatment: Graminex® RCT Fem™ UI / Graminex® PollenBerry®
- Duration : 24 weeks
- Results : Graminex® RCT Fem™ UI had 65,1% improvements in daily urinary leakage volume at week 24



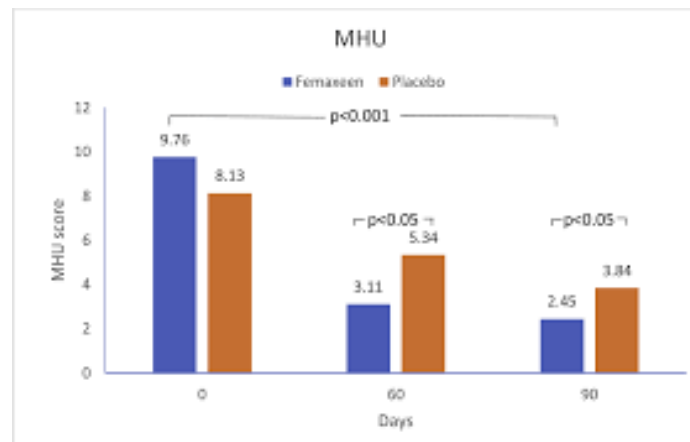


Urinary incontinence: study 2

Evaluation of Femaxeen for control of urinary incontinence in women: A randomized, double-blind, placebo-controlled study

Palacios et al., Maturitas, 2020

- Size : 76 women (average age: 56)
- Treatment: pollen extract with pumpkin seed oil
- Duration : 90 days
- Results : significant incontinence reduction in treatment group compared to placebo





Menopause

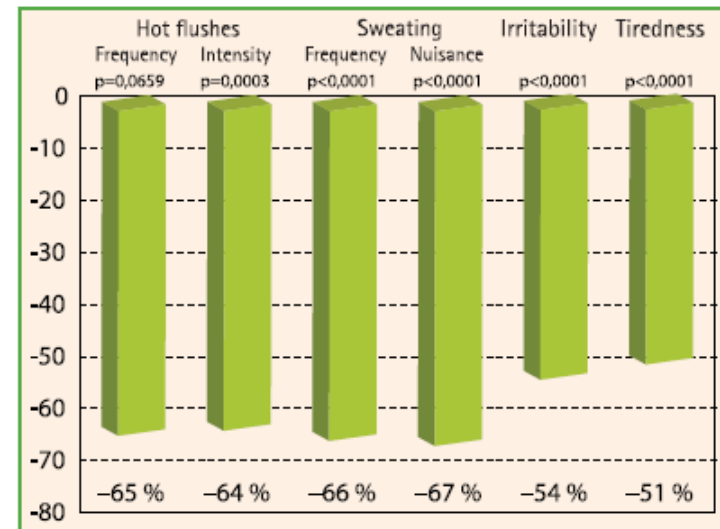


Menopause: study 1

Assessment of the tolerance and effectiveness of a food supplement Sérélys (Femal) for menopausal women

Elia et al., Genesis, 2008

- Size : 373 women (average age: 54.4)
- Daily dosage : 40 mg pollen extract, 120 mg pistil extract
- Duration : 12 weeks
- Results : > 60% reduction in hot flushes and sweating





Menopause: study 2

Femal, a herbal remedy made from pollen extracts, reduces hot flushes and improves quality of life in menopausal women: a randomized, placebo-controlled, parallel study

Winther et al., Climacteric, 2005

- Size : 54 women (average age: 51)
- Daily dosage : 40 mg pollen extract, 120 mg pistil extract
- Duration : 3 months
- Results : the pollen extract Femal significantly reduces hot flushes and certain other menopausal symptoms when compared to placebo

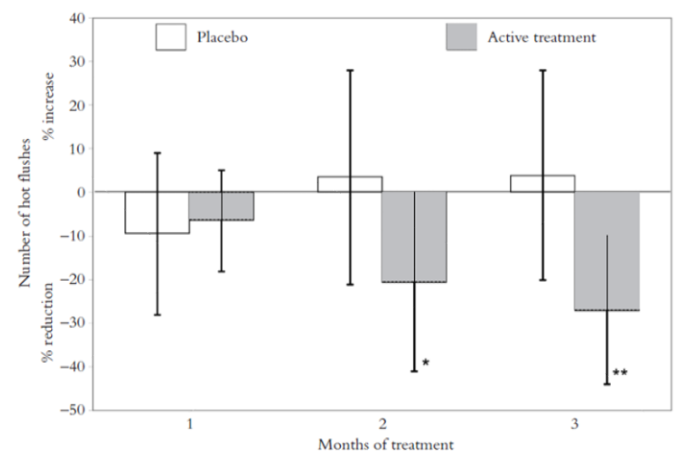


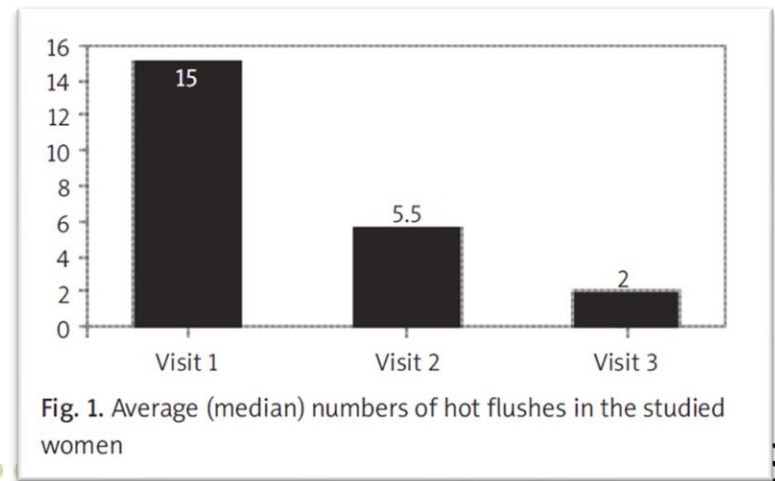
Figure 2 The percentage change in the number of hot flushes after 1, 2 and 3 months of treatment, recorded from diaries in patients on placebo ($n=27$) and patients on active treatment ($n=26$). Data are given as mean values and 95% confidence intervals. * $p < 0.021$ vs. initial values; ** $p < 0.001$ vs. initial values and $p < 0.026$ vs. 3-month placebo



Menopause: study 3

Assessment of quality of life in women using Femelis Meno (drug) *Paszkowski et al., Menopause Rev, 2018*

- Size : 50 women (average age: 54)
- Daily dosage : 40 mg pollen extract, 120 mg pistil extract
- Duration : 3 months
- Results : significant improvement of hot flushes, night sweats and sleep disorders. No adverse effect





Thanks for your attention