

Pro-UROL

NPN 80147704

Quercetin, rye pollen extract, papain and stem bromelain tablets · CP/CPPS (NIH Category III)

Summary. Pro-UROL is a Health Canada-licensed natural health product that combines two phytotherapies named in the 2025 AUA guideline for chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS): quercetin (1,200 mg/day) and *Secale cereale* (rye) pollen extract (360 mg/day, 10:1), with papain and stem bromelain. Phytotherapy carries an AUA Conditional Recommendation (Evidence Grade B) and a CUA optional first-line recommendation (Level 2, Grade B). In placebo-controlled trials, quercetin and rye pollen extract each improved NIH-CPSI scores; Cochrane pooled phytotherapy data show a mean NIH-CPSI reduction of 5.02 points versus placebo (low certainty). No trial of the finished product has been conducted.

1. CP/CPPS: a common condition with few reliable answers

Chronic prostatitis/chronic pelvic pain syndrome (NIH Category III) affects approximately 8% of adult men in pooled population studies (range 2.2–9.7%, depending on case definition).¹⁴ In Canada, almost 9% of men report prostatitis-type symptoms in a year and about 6% find them bothersome.¹⁰ Typical presentations combine perineal, pelvic, penile or ejaculatory pain with urinary urgency or discomfort, in flares that persist for months or years.

Why antimicrobial therapy usually fails

Category III is, by definition, non-bacterial. Chronic bacterial prostatitis (Category II) accounts for fewer than 10% of chronic prostatitis presentations, yet empiric antibiotic courses remain common. Two NIH-funded randomized trials found no meaningful benefit:

Trial	Population	Intervention	Result
Nickel 2003 ¹⁵	Men with CP/CPPS; multicentre RCT	Levofloxacin vs placebo, 6 weeks	No significantly greater NIH-CPSI improvement than placebo
Alexander 2004 ¹⁶	Men with long-standing CP/CPPS; CPCRN 2×2 factorial RCT	Ciprofloxacin, tamsulosin, both, or placebo, 6 weeks	No arm substantially reduced NIH-CPSI scores versus placebo

Both the AUA (Statement 42) and the CUA (1:A) advise against repeated antimicrobial courses when cultures are negative. Pooled antibiotic effects in the Cochrane review are small (NIH-CPSI MD –2.43; low certainty).⁶

The outcome measure: NIH-CPSI

The NIH Chronic Prostatitis Symptom Index, developed and validated by the NIH Chronic Prostatitis Collaborative Research Network, is the standard endpoint in CP/CPPS trials and the measure behind every trial result in this monograph.¹¹ It has nine items in three domains: pain (items 1–4; 0–21), urinary symptoms (items 5–6; 0–10) and quality-of-life impact (items 7–9; 0–12), for a total of 0–43. A 6-point decrease is the threshold that best predicts patient-perceived improvement.⁷

Phenotype-directed care: UPOINT

Because CP/CPPS is heterogeneous, treatment is increasingly matched to six clinical domains: **U**rinary, **P**sychosocial, **O**rgan-specific, **I**nfection, **N**eurologic/systemic and **T**enderness of pelvic floor muscles. The number of positive domains correlates with symptom severity.¹⁷ In a prospective cohort of 100 men treated by UPOINT phenotype, 84% achieved a ≥6-point NIH-CPSI decrease at a median 50 weeks.⁵ Quercetin and pollen extract are typically assigned to the **Organ-specific** (prostate) domain.¹²

Where Pro-UROL fits. Pro-UROL is designed as the Organ-specific component of a UPOINT-directed plan, alongside alpha-blockade for urinary symptoms, pelvic floor physiotherapy for tenderness and psychosocial support where indicated. It is not a substitute for diagnosis or for comprehensive, phenotype-directed care.

2. Product information

Item	Detail (product licence, label and manufacturer)
Brand / NPN	Pro-UROL / NPN 80147704 (licensed 6 March 2026)
Licence holder	Aleaf Labs Inc., 47 Albert Lewis St., Markham ON L6B 0Z3
Dosage form	Oral tablet (yellow, oblong); 90 tablets per bottle (30-day supply)
Medicinal ingredients (per tablet)	Quercetin 400 mg (quercetin dihydrate, synthetic) Pollen extract 120 mg (<i>Secale cereale</i> pollen; 10:1, equivalent to 1,200 mg dried pollen) Papain 50 mg (<i>Carica papaya</i> fruit; 100,000 FCC PU) Stem bromelain 33.33 mg (<i>Ananas comosus</i> var. <i>bracteatus</i> stem; 1,200,000 FCC PU)
Daily intake (1 tablet TID)	Quercetin 1,200 mg; pollen extract 360 mg (3,600 mg dried pollen equivalent); papain 150 mg; stem bromelain 100 mg
Non-medicinal ingredients	Microcrystalline cellulose, dicalcium phosphate, croscarmellose sodium, magnesium stearate, silicon dioxide, polyvinyl alcohol, polyethylene glycol (macrogol), talc
Recommended use (licensed)	Source of antioxidants. Helps to support prostate health. Helps relieve the pain of non-bacterial chronic prostatitis. Helps relieve pain associated with chronic prostatitis to support quality of life.
Recommended dose	Men 18 years and older: 1 tablet TID, taken with food (with meals, which also makes the three daily doses easy to remember).
Duration of use	Consult a health care practitioner for use beyond 12 weeks.
Contraindication	Do not use if allergic/hypersensitive to bee products or pollen.
Cautions and warnings	Ask a health care practitioner prior to use if taking an anticoagulant/blood thinner, anti-inflammatory agents or antibiotics; with a gastrointestinal lesion/ulcer; before surgery; or with allergy to latex or fruits (e.g. avocado, banana, chestnut, passion fruit, fig, melon, mango, kiwi, pineapple, peach, tomato).
Storage	15–30 °C, away from light and moisture. Keep out of reach of children. Do not use if seal is broken.
Manufacture	Made in Canada in a GMP-certified facility from domestic and imported ingredients. Non-GMO. Halal.

3. Indication and patient selection

Pro-UROL is intended for adult men with CP/CPPS (NIH Category III: IIIA inflammatory or IIIB non-inflammatory), defined as pelvic pain or discomfort for at least 3 of the previous 6 months without demonstrable infection or other identifiable cause. CP/CPPS is a diagnosis of exclusion. The AUA 2025 guideline recommends the following evaluation before treatment (Statements 1–8):

- History, symptom review, physical examination and laboratory testing, screening for concurrent pelvic pathology and confusable disorders (Clinical Principle).
- Validated questionnaires for pain, urinary symptoms and quality of life, such as the NIH-CPSI (Clinical Principle).
- Psychosocial assessment, including anxiety, depression, stress and functional impact (Clinical Principle).
- Neurological, musculoskeletal and orthopedic screening; transrectal palpation of the pelvic floor for tenderness (Expert Opinion).
- Localization testing (pre/post-massage or two-/four-glass) when chronic bacterial prostatitis cannot be excluded; cystoscopy, urodynamics or imaging when the diagnosis is unclear.

Not indicated for acute or chronic bacterial prostatitis (NIH I–II), benign prostatic hyperplasia or prostate cancer. Phytotherapy is best positioned within individualized, phenotype-directed multimodal care (UPOINT) rather than as monotherapy for severe or refractory disease.

Patients with a history of pelvic radiation. Pro-UROL is licensed for non-bacterial chronic prostatitis only. It is not licensed for, and has not been studied in, radiation-related urinary or pelvic symptoms. A trial of a similar quercetin-based formula after prostate brachytherapy is registered (ClinicalTrials.gov NCT04252625); no results have been published to our knowledge. Quercetin is an antioxidant, and its use during active radiotherapy has not been studied. Timing relative to treatment is a matter for the treating team.

4. Guideline positioning

4.1 AUA 2025: Male Chronic Pelvic Pain, Part II (CP/CPPS treatment)⁹

Lai HH, Pontari MA, Argoff CE, et al. Recommendations paraphrased; strength and evidence grade as published. Phytotherapy row highlighted.

#	Intervention	Recommendation	Strength; evidence
17	Lifestyle modification (diet, aerobic exercise)	May be discussed	Conditional; Grade C
18	Alpha-blocker, for men with voiding symptoms	Should be offered	Moderate; Grade B
19	5-alpha reductase inhibitor, with BPH-related LUTS or enlarged prostate	May be prescribed	Expert Opinion
20	Anti-inflammatories incl. NSAIDs, within multimodal pain care	May be prescribed	Conditional; Grade B
21	Daily tadalafil, with or without ED	May be prescribed	Conditional; Grade B
22	Urinary analgesics, acetaminophen, non-opioid analgesics	May be prescribed after counselling	Clinical Principle
23	Neuropathic agents (TCAs, SSRIs, gabapentinoids)	May be prescribed	Conditional; Grade C
24	Phytotherapeutics: saw palmetto, quercetin, pollen extract, to improve pain, voiding symptoms and quality of life	May be prescribed	Conditional; Grade B
25	Cognitive behavioural therapy, as an adjunct	May be offered	Conditional; Grade C
26	Low-intensity extracorporeal shockwave therapy	Should be discussed	Moderate; Grade A
27	Transcutaneous electrical nerve stimulation (TENS)	May be offered	Conditional; Grade B
28	Acupuncture	May be offered	Conditional; Grade B
42	Repeated antimicrobial courses when cultures/STI testing are negative	Should not be used	Clinical Principle
43	Prostate surgery for pelvic pain	Should not be performed	Expert Opinion
44	Long-term oral glucocorticoids	Should not be used	Expert Opinion

4.2 CUA 2011: Prostatitis guideline (Nickel JC)¹⁰

Level of evidence : grade of recommendation (ICUD/WHO-modified Oxford system).

Intervention	CUA recommendation	Level:Grade
Phytotherapy: quercetin and pollen extract (Cernilton)	Optional first-line therapy; also within multimodal therapy	2:B (first-line); 3:C (multimodal)
Saw palmetto	Insufficient evidence for a recommendation	4:D
Alpha-blockers	Not first-line monotherapy; may benefit recent-onset, alpha-blocker-naïve men; useful for voiding symptoms within multimodal therapy	1:A (not first-line)
Antibiotics	Not recommended in long-standing, previously treated CP/CPPS or after antibiotic failure	1:A
Anti-inflammatories	Not primary therapy; adjunct within multimodal therapy	1:B; 2:C
5-ARIs, pregabalin, pentosan polysulfate	Not recommended as primary monotherapy; selected patients only	1:A
Physiotherapy, acupuncture, biofeedback	Promising; need sham-controlled trials	3:C
Individualized multimodal therapy (UPOINT)	Recommended; focused multimodal therapy appears more successful than empiric monotherapy	3:C
NIH-CPSI	Recommended for symptom evaluation and as an outcome measure	3:A

5. Clinical evidence for the active ingredients

No randomized trial of Pro-UROL as a finished product has been conducted. The trials below tested the individual ingredients, often as specific branded preparations; results may not transfer directly to this formulation.

Study	Design / population	Intervention (daily)	Duration	Key results
Shoskes 1999²	RCT, double-blind; n=30; NIH Category III	Quercetin 500 mg BID (1,000 mg/day) vs placebo	4 weeks	NIH-CPSI 21.0 → 13.1 (quercetin; significant) vs 20.2 → 18.8 (placebo; not significant). ≥25% improvement: 67% vs 20%.
Shoskes 1999, open-label extension²	Open-label; n=17	Quercetin + bromelain + papain	4 weeks	82% achieved ≥25% improvement. No control group; authors disclosed a financial interest.
Wagenlehner 2009³	Phase 3 RCT, double-blind, multicentre; n=139; inflammatory CP/CPPS (IIIA)	Cernilton (rye pollen extract) 2 capsules q8h (≈378 mg/day) vs placebo	12 weeks	NIH-CPSI pain domain −4.50 vs −2.92 (significant); total NIH-CPSI significantly improved. Responders (≥25% or ≥6-point decrease): 70.6% vs 50.0%. Adverse events minor in both arms.
Elist 2006⁴	RCT, double-blind; n=60; CP/CPPS	Prostat/Poltit pollen preparation vs placebo	6 months	Clinical improvement 73% vs 35%; complete symptom resolution 20% vs 0%.
Shoskes 2010⁵	Prospective, UPOINT-directed multimodal therapy; n=100	Phenotype-directed; quercetin used for the organ-specific domain	Median 50 weeks	84% achieved ≥6-point NIH-CPSI decrease. Total NIH-CPSI 25.2 → 13.2; pain 11.5 → 6.1; QoL 9.1 → 4.5 (all p<0.0001).
Franco 2019 (Cochrane)⁶	Systematic review; phytotherapy vs placebo (7 studies, 551 men)	Various phytotherapies	Short term	NIH-CPSI MD −5.02 (95% CI −6.81 to −3.23; 5 studies, 320 men; low certainty). Adverse events probably not increased.

5.1 Context: Cochrane short-term NIH-CPSI effects versus placebo⁶

Intervention	Mean difference (95% CI)	Studies / participants	Certainty
Phytotherapy	−5.02 (−6.81 to −3.23)	5 / 320	Low
Alpha-blockers	−5.01 (−7.41 to −2.61)	18 / 1,524	Very low
Anti-inflammatories	−2.50 (−3.74 to −1.26)	7 / 585	Low
Antibiotics (quinolones)	−2.43 (−4.72 to −0.15)	5 / 372	Low

Alpha-blockers carried a higher risk of adverse events (RR 1.60, 95% CI 1.09 to 2.34; mainly dizziness and postural hypotension). A 6-point decrease in total NIH-CPSI is the threshold that best predicts patient-perceived improvement.⁷

5.2 Pro-UROL dosing compared with trial doses

Ingredient	Trial daily dose	Pro-UROL daily dose	Comment
Quercetin	1,000 mg (Shoskes 1999)	1,200 mg	20% above the studied dose; synthetic quercetin dihydrate
Rye pollen extract	≈378 mg Cernilton (Wagenlehner 2009)	360 mg (10:1; 3,600 mg dried pollen equivalent)	Similar milligram amount; Cernilton is a proprietary standardized extract, so equivalence is not established
Papain	Not studied alone in CP/CPPS	150 mg (100,000 FCC PU per tablet)	Included in the open-label quercetin combination
Stem bromelain	Not studied alone in CP/CPPS	100 mg (1,200,000 FCC PU per tablet)	Proposed to aid quercetin absorption; unproven

6. Formulation rationale: why these four ingredients

Quercetin: the anchor ingredient

Quercetin is a plant flavonol and the ingredient with the most direct CP/CPPS evidence: the placebo-controlled trial summarized in Section 5, and a dedicated review by the trial investigators describing its use within UPOINT-directed care.^{2,12} Its proposed mechanisms are anti-inflammatory and antioxidant: in experimental models quercetin modulates NF-κB and MAPK signalling and reduces TNF-α, IL-1β and IL-6;¹⁸ in human mast cells it inhibits release of inflammatory mediators and cytokines more effectively than cromolyn.¹⁹ Mast cells have been proposed as contributors to CP/CPPS pain. These are laboratory findings and explain plausibility, not clinical efficacy.

Rye pollen extract: the second evidence-based phytotherapy

Secale cereale pollen extract is the second phytotherapy named in the AUA and CUA guidelines, supported by two placebo-controlled trials (Wagenlehner 2009; Elist 2006).^{3,4} Pro-UROL provides 360 mg daily of a 10:1 extract, a milligram amount close to the ≈378 mg/day of Cernilton used in the largest trial.

Bromelain and papain: the proteolytic-enzyme combination

Oral quercetin has low bioavailability. Pairing quercetin with the proteolytic enzymes bromelain (pineapple stem) and papain (papaya) is the formulation described by the investigators of the original quercetin trial, and the combination tested in their open-label extension (82% of 17 men improved by ≥25%).^{2,20} Enhanced absorption is the stated rationale; it has not been demonstrated in a pharmacokinetic study of this formulation. Bromelain also has documented anti-inflammatory and anti-oedematous properties.²¹ Both enzymes add bleeding and latex–fruit allergy considerations (Section 7).

How Pro-UROL compares with generic "prostate support" products

Feature	Pro-UROL	Typical prostate supplement
Target condition	Licensed for the pain of non-bacterial chronic prostatitis (CP/CPPS)	Usually positioned for BPH or general prostate health
Guideline-named actives	Quercetin and rye pollen extract, both named in AUA 2025 Statement 24	Often saw palmetto, which the CUA rates 4:D for CP/CPPS
Dose disclosure	Every active declared in mg per tablet; daily quercetin above the trial dose	Some list proprietary blends without per-ingredient amounts
Formulation lineage	The quercetin + bromelain + papain combination studied open-label, plus rye pollen extract	Varies
Regulatory status	Health Canada NPN 80147704; made in Canada in a GMP-certified facility	Varies

7. Safety, interactions and tolerability

- **Contraindication:** allergy or hypersensitivity to bee products or pollen.
- **Anticoagulants/antiplatelets:** bromelain and papain may increase bleeding risk; a case report associated quercetin with a raised INR on warfarin. Monitor, and consider stopping before elective surgery.
- **Drug metabolism:** quercetin modulates CYP3A4 and P-glycoprotein in vitro; clinical significance is uncertain. Review narrow-therapeutic-index medicines.
- **Fluoroquinolones:** in vitro data suggest quercetin may interfere with fluoroquinolone activity. Pro-UROL's licence carries a general antibiotic caution; separating doses or avoiding concurrent use is prudent.
- **Renal impairment:** nephrotoxicity has been reported with high-dose intravenous quercetin, not oral use. Use judgment in significant renal disease.
- **Allergy:** papain and bromelain carry latex–fruit cross-reactivity (see licensed cautions).
- **Tolerability:** in the trials above, adverse events were infrequent and minor (mainly gastrointestinal). Oral quercetin up to 1,000 mg/day for 12 weeks is generally well tolerated.⁸

8. Dosing, monitoring and duration

Time point	Action
Baseline	Confirm CP/CPPS diagnosis; record NIH-CPSI total and domain scores; review medications against cautions.
Weeks 4–6	Check tolerability and adherence (1 tablet TID with meals); repeat NIH-CPSI if useful.
Week 12	Repeat NIH-CPSI. A ≥6-point decrease indicates a clinically meaningful response. If there is no meaningful response, stop and consider other phenotype-directed options.
Beyond 12 weeks	Continue only under practitioner supervision (licensed duration statement).

9. Limitations of the evidence

- No trial of the finished Pro-UROL formulation.
- Ingredient trials are small (n=30 to 139) and short (4 weeks to 6 months); the quercetin RCT has not been replicated at scale.
- The pollen extract evidence is largely from Cernilton, a proprietary standardized extract; the Wagenlehner trial enrolled IIIA patients only.
- AUA and Cochrane rate the phytotherapy evidence as Grade B and low certainty, respectively. Guidelines name ingredients, not brands.

10. Supply and manufacture

Aleaf Labs developed Pro-UROL with physicians and botanists after seeing men with CP/CPPS go without because comparable formulas in Canada were on backorder. It is manufactured in Canada in a GMP-certified facility to give Canadian patients a steady supply. Patient handouts, printed monographs and a call from an Aleaf Labs authorized representative are available free at aleaflabs.com/pages/practitioners. Product page: prourol.ca. Questions: support@aleaflabs.com.

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