semaine

DESIGN PHILOSOPHY:

Urinary Tract Cleanse & Protect

Perspective

- Women are at significantly higher risk for urinary tract infections (UTIs) relative to men. The risk of UTIs increases with sexual activity, but also steadily throughout life.[1]
- UTIs are becoming increasingly resistant to antibiotics.[2]
- Frequent antibiotic usage is increasingly understood as carrying health risks by altering commensal gut bacteria and the intestinal microbiome.[3]
- One of the initial immune responses to a UTI is to increase shedding of the bladder lining. This helps remove the microbial infection but makes the bladder more vulnerable to salt and toxins in urine. This potentially leads to long-term pain and underlying damage to the bladder.[8]
- Damage to the bladder wall through recurrent UTIs can increase the risk for interstitial cystitis and bladder pain syndrome, which is more common in women.[9]
- Recurrent UTIs are correlated with incontinence in post-menopausal women.[4, 5]
- In elderly patients, UTIs are extremely common and pose significant mental and physical costs as they frequently result in symptoms associated with dementia.[6-7]
- UTIs impose a significant disease burden on women and the U.S. medical system. UTIs alone are responsible for almost 6% of all medical visits.[10]
- Epidemiological studies have long identified diets with more fruits and vegetables as lowering UTI disease risk.[11–13]

- Polyphenols in cranberry juice have been shown to reduce UTI risk in a meta-analysis of published research.[14]
- American Urological Association guidelines identify the need for additional alternatives to antibiotic treatment.[15]
- Recurrent UTIs are also associated with an increased risk of kidney stones, and kidney stones increase UTI risk. Resolving kidney stones frequently helps resolve UTIs.[16]
- Plant sources have been shown to help resolve kidney stones and prevent recurrence.[17]

What Urinary Tract Cleanse & Protect Is Not

- **Not alternative medicine.** Urinary Tract Cleanse & Protect is grounded in science and medicine. It relies on clinical data and is designed to be supported by rigorous clinical trials.
- **Not a cure.** Urinary Tract Cleanse & Protect does not cure diseases, and will not claim to, but rather provides support for individuals with recurrent UTIs or who are at higher risk for UTIs while also reducing the risk of kidney stone accumulation.
- **Not a quick fix.** Changes to diet, environment, and exercise are frequently necessary to reduce UTI risks, and Urinary Tract Cleanse & Protect is designed to be a supportive addition to lifestyle changes.

Product Profile for Urinary Tract Cleanse & Protect

Design Objectives

- Provide cranberry polyphenols at levels that are supported by published experiments and shown to reduce UTIs (cranberry phytosome)
- Reduce the likelihood of kidney stone accumulation using antiurolithiatic extracts (hibiscus)
- Ensure capsules are small enough to be easily consumed by an aging population

Product Formulation

Cranberry phytosome

Rationale:

- Cranberry extracts have been widely used to address UTIs and are frequently used by patients who have recurrent UTIs[18-19]
- Cranberry contains multiple polyphenol compounds that have been identified to affect microbial adhesion and to disrupt biofilms[20]
- Cranberry extracts can vary significantly in quality, and it is important to use specific products that have been well studied and provide consistent polyphenol levels

Safety:

- Well tolerated with no side effects

Urinary Tract Cleanse & Protect shows it is possible to rationally design a product that supports the physiological factors linked with improved bladder health, reduced kidney stone and UTI risk, and that does so in a safe manner.

Semaine Health Co. Philosophy

- Rooted in a patient- and advocacy-focused approach with deep relationships with advocates and patient groups
- Focused on continuous engagement with medical professionals to guide product development and provide useful information to customers
- Committed to using clinical trials to validate claims

Form and Dosage:

- Dosage: 120 mg of cranberry phytosome (standardized relative to the pro-anthocyanidin levels)
- Justification: Recent study using 120 mg of cranberry phytosome improved urinary health following catheterization to the same extent as nitrofurantoin[21]
- Form: Anthocran® phytosome sourced from Indena; this is a standardized cranberry extract that has been encapsulated in a fat to create a structure similar to a liposome and increase bioavailability

Hibiscus

Rationale:

- Hibiscus has long been used to reduce kidney stones by reducing calcium oxalate retention in the kidney[17, 22, 23]
- Polyphenols in hibiscus have also been shown to reduce UTI occurrence[24]
- There is a strong link between kidney stones and recurrent UTIs, which makes it important to protect against both[16]

Safety:

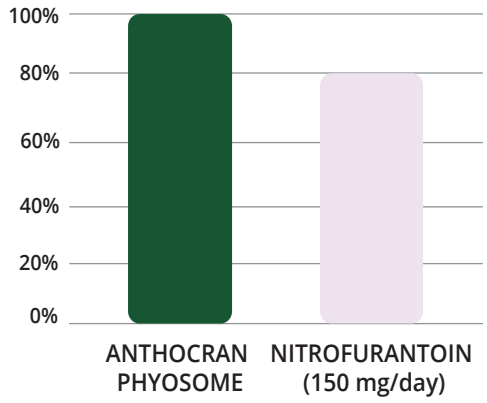
- Well tolerated in the general population; potential concern for pregnant women

Form and Dosage:

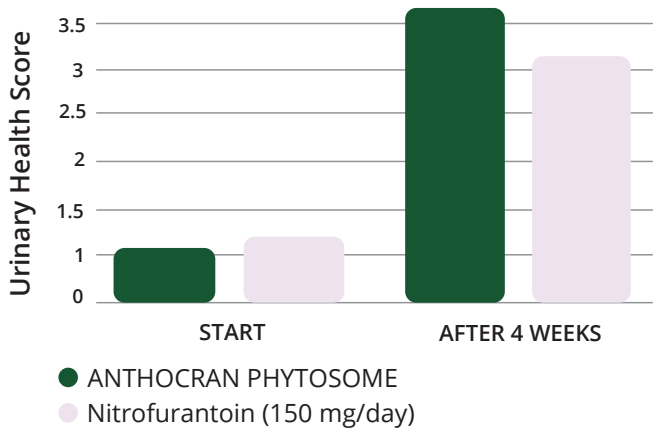
- Dosage: 200 mg of hibiscus extract, containing a minimum of 20 mg of polyphenols
- Justification: Doses of hibiscus polyphenols up to 250 mg have been used safely for extended durations[25]
- Form: Extract standardized to 10% polyphenol content and sourced from Nexira in France

Pilot Clinical Trial

In an RCT crossover trial, participants were administered 120 mg of cranberry phytosome. Urine was collected from the participants, and after 12 hours, microbial growth in the urine was reduced 55% compared with the control. Furthermore, 100% of the participants using the cranberry phytosome were UTI-free three months after they stopped taking the supplement.[20]



In a trial with 64 participants who had recently undergone post-surgical catheterization (a procedure with a high probability of causing a UTI), 120 mg of cranberry phytosome was able to improve urinary health to the same extent as a common antibiotic (nitrofurantoin).[21]



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