

Exclusion Criteria

Medical History	<ul style="list-style-type: none"> • Cancer or known pre-malignant conditions, including skin cancer; • bladder calculus, tuberculous cystitis; neurologic disease affecting bladder function; • peptic ulcer disease, inflammatory bowel disease or gastrointestinal bleeding.
Current Medical Conditions	<ul style="list-style-type: none"> • Immunocompromised condition, including treatment with immunosuppressive agents, or known positive for HIV; active tuberculosis; • active urethral or ureteral calculi, urethral diverticulum; • patients with hypertension not adequately controlled with medication; • unevaluated suspicious prostate exam; • (women only) pregnant or breastfeeding, active vaginitis.
Treatment History	<ul style="list-style-type: none"> • Initiation of any new medications for IC/PBS or any intravesical treatment in past 4 weeks. • Cyclophosphamide; intravesical BCG or botulinum toxin injections for voiding symptoms in past 24 weeks; current antibiotic therapy.
Current Treatment	<ul style="list-style-type: none"> • Systemic steroid treatment at any dose; • patient currently taking H2 blockers or proton pump inhibitors; • (men only) treatment for chronic bacterial prostatitis; • active neurostimulator.
Procedure History	<ul style="list-style-type: none"> • Pelvic radiation therapy; augmentation cystoplasty, cystectomy, or cystolysis; neurectomy; • treatment for genital tract dysplasia or genital warts or genital herpes; • hydrodistention within the past 12 weeks or urethral dilation within the past six weeks; • urinary incontinence surgery; other bladder or urethral surgery in past 24 weeks; • vaginal delivery or C-section, transvaginal surgery, hysterectomy, or prolapsed surgery in past 24 weeks; • TURP, TUIP, TUIBN, TUMT, TUNA, balloon dilation of the prostate, open prostatectomy or any other prostate or treatment, such as cryotherapy or thermal therapy, in past 24 weeks.
Laboratory Tests	<ul style="list-style-type: none"> • abnormal PAP smear exam within the past 12 months; • liver function test or creatinine greater than 2x the upper limit of normal; • any leukopenia (absolute neutrophil count <1,500/μL), thrombocytopenia (platelet count <150,000/microL), or anemia (hemoglobin <12 or <11 g/dL in men and in women respectively.); • seropositive for Hepatitis B surface antigen (or Hepatitis B surface antibody if not previously vaccinated); Hepatitis C antibody, or HIV antigen or antibody; • positive urine culture during the past 6 weeks.