I C C T G ICCTG PROTOCOL #1	Eligibility Confirmation and Randomization	Patient ID: ___ ___ ___ ___ ___ Patient Initials: ___ ___ ___ Clinical Center: ___ Contact Week: 0 Date: __ __ / __ __ / __ __ month day year RC ID: ___ ___ ___ ___

(To be completed by Research Coordinator and Investigator at Baseline 2.)

1. What is the date of the informed consent? Date: __ __ / __ __ / __ __ (month day year)

INCLUSION CRITERIA: (See Inclusion form) (Answers to questions #2 through #4 must be "Yes")

2. Has the patient (male and female) agreed to use an effective method of birth control? ❑1 Yes ❑0 No

3. Based on the Baseline Symptoms questionaires given at both the Baseline 1 (B1) and Baseline 2 (B2) visits, does the patient meet eligibility criteria by having obtained a pain/discomfort score of at least 4 (Question #1) AND urinary frequency of at least 11 times within 24 hours (Question #3) at *both visits .* ❑1 Yes ❑0 No

4. Have the urinary symptoms persisted for at least the previous 24 weeks? (See Question #4 of Baseline Symptoms 1) ❑1 Yes ❑0 No

EXCLUSION CRITERIA: (See Exclusion form) (Answers to questions #5 through #35 must be "No")

5. Is there any reason to suspect the patient will not be compliant due to a medical or psychological problem? ❑1 Yes ❑0 No

6. Is the patient currently participating in another intervention study? ❑1 Yes ❑0 No

7. Is the patient planning a change in residence outside the driving distance of the ICCTG network within the next 24 weeks? ❑1 Yes ❑0 No

Prior Treatments:

8. Does the patient have a history of having been previously treated with Cytoxan® (cyclophosphamide)? ❑1 Yes ❑0 No

9. Does the patient have a history of pelvic radiation treatment? ❑1 Yes ❑0 No

10.	Has the patient ever been treated with Elmiron® at a dose of at least 100 mg 3 times a day for more than 12 consecutive weeks?	❑1 Yes	❑0 No
11.	Has the patient ever been treated with hydroxyzine at a dose greater than 10 mg per day for more than 12 consecutive weeks?	❑1 Yes	❑0 No

Prior Procedures:

12.	Has the patient had augmentation cystoplasty?	❑1 Yes	❑0 No
13.	Has the patient had a cystectomy or cystolysis?	❑1 Yes	❑0 No
14.	Has the patient had any neurectomy or implanted peripheral nerve stimulator which has affected bladder function?	❑1 Yes	❑0 No

Prior Conditions/Diseases:

15.	Does the patient have a history of a bladder calculus?	❑1 Yes	❑0 No
16.	Does the patient have a history of tuberculous cystitis?	❑1 Yes	❑0 No
17.	Does the patient have a history of neurologic disease or diabetic cystopathy?	❑1 Yes	❑0 No
18.	Does the patient have a history of malignant bladder tumors?	❑1 Yes	❑0 No
19.	Does the patient have a history of urethral cancer?	❑1 Yes	❑0 No

Current Conditions/Medications:

20.	Has the patient recorded one or more voids greater than 350cc on the Voiding Diary?	❑1 Yes	❑0 No
21.	Has the patient had liver function tests (AST/SGOT, ALT/SGPT, glutamyltransferase, and alkaline phosphatase) which are greater than 1.5 times the institution's upper limits of nomal? (See Lab Results form)	❑1 Yes	❑0 No
22.	Has the patient had blood coagulation tests (PTT, PT, and platelets) during the screening phase which are outside the eligibility criteria? (See Lab Results form)	❑1 Yes	❑0 No

23. Does the patient currently have an active urethral calculus? ❑1 Yes ❑0 No

24. Does the patient currently have an active ureteral calculus? ❑1 Yes ❑0 No

25. Does the patient have symptomatic urethral diverticulum? ❑1 Yes ❑0 No

26. Does the patient have any known allergies to Elmiron® or hydroxyzine? ❑1 Yes ❑0 No

27. Is the patient currently taking Tagamet® (cimetidine) or intravesical heparin? (See Exclusionary/Restricted Medications Table and MOP) ❑1 Yes ❑0 No

28. Is the patient currently taking aspirin, acetaminophen, aspirin replacement products (NSAIDS), products containing brompheniramine, diphenhydramine, or chlorpheniramine outside the restrictive criteria defined in the protocol? (See Exclusionary/Restricted Medication Table and MOP) ❑1 Yes ❑0 No

WOMEN ONLY: (for male patients, indicate n/a)

29. Has the patient had uterine, cervical or vaginal cancer during the past 3 years? ❑1 Yes ❑0 No ❑9 n/a

30. Does the patient have active vaginitis? ❑1 Yes ❑0 No ❑9 n/a

31. Is the patient pregnant? ❑1 Yes ❑0 No ❑9 n/a

Date of negative pregnancy test, if applicable : Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)

32. Is the patient breast-feeding? ❑1 Yes ❑0 No ❑9 n/a

MEN ONLY: (for female patients, indicate n/a)

33. Did this patient have a residual urine volume greater than 150 cc as measured by ultrasound or catheter within the past 4 weeks? ❑1 Yes ❑0 No ❑9 n/a

34. Has the patient ever had the following surgical procedures: TURP, TUIP, TUIBN, TUMT, TUNA, balloon dilation of the prostate, open prostatectomy, or any other prostate surgery or treatment such as cryotherapy or thermal therapy? ❑1 Yes ❑0 No ❑9 n/a

35. Is the patient being treated for chronic bacterial prostatitis as documented by a positive urine culture? ❑1 Yes ❑0 No ❑9 n/a

DEFERRAL CRITERIA: (See Deferral form)

36. Was the patient deferred during the screening phase of this study for having started any new medications for interstitial cystitis? ❑1 Yes ❑0 No

*If **YES**, indicate date of last change in dose:* __ __ / __ __ / __ __ (month / day / year)
(4 weeks or more must have elapsed since the date of the most recent change in dose for any IC medications.)

37. Was the patient deferred during the screening phase of this study because the patient had undergone urethral dilation, cystometrogram, urodynamics, bladder cystoscopy/hydrodistention under general or regional anesthesia, or bladder biopsy under general or regional anesthesia? ❑1 Yes ❑0 No

*If **YES**, indicate date of the most recent procedure:* __ __ / __ __ / __ __ (month / day / year)
(6 weeks or more must have elapsed since the date of the most recent procedure.)

38. Was the patient deferred during the screening phase of this study for a positive urine culture and/or clinical evidence of bacterial urinary tract infection (UTI)? ❑1 Yes ❑0 No

*If **YES**, indicate date of negative urine culture:* __ __ / __ __ / __ __ (month / day / year)
(6 weeks or more must have elapsed since this date.)

39. Was the patient deferred during the screening phase of this study because of gross hematuria? ❑1 Yes ❑0 No

*If **YES**, Indicate date of last episode:* __ __ / __ __ / __ __ (month / day / year)
(12 weeks or more must have elapsed since this date.)

40. Was the patient deferred during the screening phase of this study for an active genital herpes episode? ❑1 Yes ❑0 No

*If **YES**, indicate date last active herpes episode resolved:* __ __ / __ __ / __ __ (month / day / year)
(12 weeks or more must have elapsed since this date.)

41. Was the patient deferred during the screening phase of this study for having received treatment with Elmiron® or hydroxyzine? ❑1 Yes ❑0 No

*If **YES**, indicate the most recent date of last dose:* __ __ / __ __ / __ __ (month / day / year)
(4 weeks or more must have elapsed since this date.)

42. Was the patient deferred during the screening phase of this study for having received intravesical treatment with BCG? ❑1 Yes ❑0 No

*If **YES**, indicate the date of last dose:* __ __ / __ __ / __ __ (month / day / year)
(24 weeks or more must have elapsed since this date.)

43. Was the patient deferred during the screening phase of this study for having received intravesical treatment **other than** BCG? ❑1 Yes ❑0 No

*If **YES,** indicate the most recent date of last dose:* __ __ / __ __ / __ __ (month / day / year)
(12 weeks or more must have elapsed since this date.)

44. Was the patient deferred during the screening phase of this study for having had any of the following surgeries during the previous 24 weeks: urinary incontinence, cystocele (bladder hernia repair), or rectocele (rectal hernia repair)? ❑1 Yes ❑0 No

*If **YES**, indicate the date of the most recent surgery:* __ __ / __ __ / __ __ (month / day / year)
(24 weeks or more must have elapsed since this date.)

FEMALE ONLY: (for male patients, indicate n/a)

45. Was the patient deferred during the screening phase of this study for having had any of the following surgeries during the previous 24 weeks: transvaginal, prolapse, or any form of hysterectomy? ❑1 Yes ❑0 No ❑9 n/a

*If **YES,** Indicate the date of the most recent surgery:* __ __ / __ __ / __ __ (month / day / year)
(24 weeks or more must have elapsed since this date.)

46. Was the patient deferred during the screening phase of this study for having had a vaginal delivery or a cesarean section within the previous 24 weeks? ❑1 Yes ❑0 No ❑9 n/a

*If **YES,** Indicate the date of the event:* __ __ / __ __ / __ __ (month / day / year)
*(If **YES**, 24 weeks or more have elapsed since this date.)*

MALE ONLY: (For female patients, indicate N/A)

50. Was the patient deferred for TURP, TUIP, TUIBN, TUMT, TUNA, balloon dilation of the prostate, open prostatectomy, or any other prostate surgery or treatment such as cryotherapy or thermal therapy? ❑1 Yes ❑0 No ❑9 n/a

*If **YES,** Indicate the date of the procedure:* __ __ / __ __ / __ __ (month / day / year)
*(If **YES**, 26 weeks or more have elapsed since this date.)*

End of Deferral Criteria, continue with Eligibility Confirmation

47. Does the patient meet all of the eligibility criteria including being at least 18 years of age? ❑1 Yes ❑0 No

48. Indicate the registering physician's I.D. number: __ __ __ __

49. Perform computer randomization and record randomization number: __ __ __ __ __

Exclusionary and Restricted Medications

Product List	Restrictive Criteria	Generic Name	Selected Brand Names
CIMETIDINE	**cannot use**	cimetidine	Tagamet® (the only U.S. brand)
INTRAVESICAL HEPARIN	**cannot use** (Instilled into the urinary bladder)	not applicable	not applicable
ASPIRIN PRODUCTS	Chronic use***** of greater than one gram of aspirin within a 24 hour period.	Acetylsalicylic acid	Anacin®, Bayer®, Bufferin®, Ecotrin®, Excedrin®
ASPIRIN REPLACEMENT PRODUCTS AND NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)	Chronic use***** totaling more than the maximum single dose allowed by the PDR for prescription use within a 24 hour period.	acetaminophen, celecoxib, declofenac, diclofenac, etodolac, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac tromethamine, meclofenamate sodium, mefenamic acid, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, tolmetin sodium,	Actron®, Advil®, Aleve®, Feldene®, Indocin®, Midol®, Motrin®, Relafen®, Tylenol®
SEDATING HISTAMINE-1 RECEPTOR ANTAGONISTS	Chronic use***** of only those products containing diphenhydramine, brompheniramine, or chlorpheniramine. Treatment of isolated incidences, a cold for instance, is acceptable. Topical products are also acceptable.	brompheniramine, diphenhydramine, chlorpheniramine	Dimetane®, Allerest®, Contact®, Sudafed®, Excedrin PM®, Benadryl®, Unisom®

* Chronic use: More than 3 days within a 7 day week.