

Exclusion Criteria  
(Administrative)

Patient ID: \_\_\_\_\_  
Patient Initials: \_\_\_\_\_  
Clinical Center: \_\_\_\_\_  
Contact Week: 0  
Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
                  month      day      year  
RC ID: \_\_\_\_\_

(Patient Interview completed at the Baseline 1 and 2 visits)

**EXCLUSION CRITERIA: (All responses must be “No”)**

- 1. Are you currently participating in another intervention study? <sub>1</sub> Yes <sub>0</sub> No
- 2. Are you planning a change in residence outside the driving distance of the ICCTG network within the next 24 weeks? <sub>1</sub> Yes <sub>0</sub> No

**Prior Treatments:**

- 3. Have you ever been treated with Cytoxan® (cyclophosphamide)? <sub>1</sub> Yes <sub>0</sub> No
- 4. Have you ever had pelvic radiation treatment? <sub>1</sub> Yes <sub>0</sub> No
- 5. Have you ever been treated with Elmiron® at a dose of at least 100 mg 3 times a day for more than 12 consecutive weeks? <sub>1</sub> Yes <sub>0</sub> No
- 6. Have you ever been treated with hydroxyzine at a dose greater than 10 mg once a day for more than 12 consecutive weeks? <sub>1</sub> Yes <sub>0</sub> No

**Prior Procedures:**

- 7. Have you had augmentation cystoplasty? <sub>1</sub> Yes <sub>0</sub> No
- 8. Have you had a cystectomy or cystolysis? <sub>1</sub> Yes <sub>0</sub> No
- 9. Have you had a neurectomy or implanted peripheral nerve stimulator which has affected bladder function? <sub>1</sub> Yes <sub>0</sub> No

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### Prior Conditions/Diseases:

10. Have you ever had a bladder calculus? <sub>1</sub> Yes <sub>0</sub> No
11. Have you ever had tuberculous cystitis? <sub>1</sub> Yes <sub>0</sub> No
12. Have you ever had neurologic disease or diabetic cystopathy? <sub>1</sub> Yes <sub>0</sub> No
13. Have you ever had malignant bladder tumors? <sub>1</sub> Yes <sub>0</sub> No
14. Have you ever had urethral cancer? <sub>1</sub> Yes <sub>0</sub> No

### Current Conditions/Medications:

15. Do you currently have an active urethral calculus? <sub>1</sub> Yes <sub>0</sub> No
16. Do you currently have a ureteral calculus? <sub>1</sub> Yes <sub>0</sub> No
17. Do you have symptomatic urethral diverticulum? <sub>1</sub> Yes <sub>0</sub> No
18. Do you have any known allergies to Elmiron® or hydroxyzine? <sub>1</sub> Yes <sub>0</sub> No
19. Are you currently taking Tagamet® (cimetidine) or intravesical heparin?  
(See Exclusionary/Restricted Medication Table and MOP) <sub>1</sub> Yes <sub>0</sub> No
20. Are you currently taking more than one gram of aspirin per day for more than three days out of seven?  
(See Exclusionary/Restricted Medication Table and MOP) <sub>1</sub> Yes <sub>0</sub> No
21. Are you currently taking more than one maximum allowable dose per day of acetaminophen or aspirin replacement products (NSAIDS) for more than three days out of seven?  
(See Exclusionary/Restricted Medication Table and MOP) <sub>1</sub> Yes <sub>0</sub> No
22. Are you currently taking products containing brompheniramine, diphenhydramine, or chlorpheniramine for more than three days out of seven?  
(See Exclusionary/Restricted Medication Table and MOP) <sub>1</sub> Yes <sub>0</sub> No

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### **WOMEN ONLY:**

23. Have you had uterine, cervical or vaginal cancer during the past 3 years? <sub>1</sub> Yes <sub>0</sub> No
24. Do you have active vaginitis? <sub>1</sub> Yes <sub>0</sub> No
25. Are you pregnant? <sub>1</sub> Yes <sub>0</sub> No
26. Are you breast-feeding? <sub>1</sub> Yes <sub>0</sub> No

### **MEN ONLY:**

27. Have you 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? <sub>1</sub> Yes <sub>0</sub> No
28. Are you currently being treated for chronic bacterial prostatitis as documented by a positive urine culture? <sub>1</sub> Yes <sub>0</sub> No

### **EXCLUSION QUESTIONS FOR THE BASELINE 2 VISIT ONLY:**

29. Has the patient recorded one or more voids greater than 350cc on the Voiding Diary? <sub>1</sub> Yes <sub>0</sub> No
30. Has the patient had liver function tests (AST/SGOT, ALT/SGPT, glutamyltransferase, and alkaline phosphatase) within the past 4 weeks which are greater than 1.5 times the institution's upper limits of normal? (See Lab Results form) <sub>1</sub> Yes <sub>0</sub> No
31. Has the patient had blood coagulation tests (PTT, PT, and platelets) within the past 4 weeks which are outside the institution's normal limits? (See Lab Results form) <sub>1</sub> Yes <sub>0</sub> No

**If a "YES" response is checked for any question, the patient is NOT eligible.  
If eligible, continue with the screening process.**

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### Exclusionary and Restricted Medications

Product List	Restrictive Criteria	Generic Name	Selected Brand Names
<b>CIMETIDINE</b>	<b>cannot use</b>	cimetidine	Tagamet® (the only U.S. brand)
<b>INTRAVESICAL HEP-ARIN</b>	<b>cannot use</b> (Instilled into the urinary bladder)	not applicable	not applicable
<b>ASPIRIN PRODUCTS</b>	Chronic use* of greater than one gram of aspirin within a 24 hour period.	Acetylsalicylic acid	Anacin®, Bayer®, Bufferin®, Ecotrin®, Excedrin®
<b>ASPIRIN REPLACEMENT PRODUCTS AND NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs)</b>	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®
<b>SEDATING HISTAMINE-1 RECEPTOR ANTAGONISTS</b>	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.