

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? ☐₁ Yes ☐₀ No
2. Are you planning a change in residence outside the driving distance of the ICCTG network within the next 24 weeks? ☐₁ Yes ☐₀ No

Prior Treatments:

3. Have you ever been treated with Cytoxan® (cyclophosphamide)? ☐₁ Yes ☐₀ No
4. Have you ever had pelvic radiation treatment? ☐₁ Yes ☐₀ 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? ☐₁ Yes ☐₀ 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? ☐₁ Yes ☐₀ No

Prior Procedures:

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

Exclusion Criteria (Administrative)

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Prior Conditions/Diseases:

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

Current Conditions/Medications:

- | | | |
|--|---|--|
| 15. Do you currently have an active urethral calculus? | <input type="checkbox"/> ₁ Yes | <input type="checkbox"/> ₀ No |
| 16. Do you currently have a ureteral calculus? | <input type="checkbox"/> ₁ Yes | <input type="checkbox"/> ₀ No |
| 17. Do you have symptomatic urethral diverticulum? | <input type="checkbox"/> ₁ Yes | <input type="checkbox"/> ₀ No |
| 18. Do you have any known allergies to Elmiron® or hydroxyzine? | <input type="checkbox"/> ₁ Yes | <input type="checkbox"/> ₀ No |
| 19. Are you currently taking Tagamet® (cimetidine) or intravesical heparin? (See Exclusionary/Restricted Medication Table and MOP) | <input type="checkbox"/> ₁ Yes | <input type="checkbox"/> ₀ 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) | <input type="checkbox"/> ₁ Yes | <input type="checkbox"/> ₀ 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) | <input type="checkbox"/> ₁ Yes | <input type="checkbox"/> ₀ 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) | <input type="checkbox"/> ₁ Yes | <input type="checkbox"/> ₀ No |

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WOMEN ONLY:

23. Have you had uterine, cervical or vaginal cancer during the past 3 years? ☐₁ Yes ☐₀ No
24. Do you have active vaginitis? ☐₁ Yes ☐₀ No
25. Are you pregnant? ☐₁ Yes ☐₀ No
26. Are you breast-feeding? ☐₁ Yes ☐₀ 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? ☐₁ Yes ☐₀ No
28. Are you currently being treated for chronic bacterial prostatitis as documented by a positive urine culture? ☐₁ Yes ☐₀ 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? ☐₁ Yes ☐₀ 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) ☐₁ Yes ☐₀ 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) ☐₁ Yes ☐₀ 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 |
|---|---|---|--|
| CIMETIDINE | cannot use | cimetidine | Tagamet® (the only U.S. brand) |
| INTRAVESICAL HEP-ARIN | 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 REPLACE-MENT 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.