Managing chronic bladder pain in patients who are diagnosed with interstitial cystitis (IC)

**ELMIRON® Patient Treatment Journey**

**HEALTHCARE PROFESSIONAL**

- **Basic Assessment, Diagnostic Evaluation, and Beginning Therapy**
  - Perform careful history, physical exam, urinalysis and culture, and pain evaluation. In patients with a history of smoking and/or microhematuria, consider urine cytology.
  - Have patient complete IC Symptom Questionnaire or O’Leary-Sant IC Symptom and Problem Index to establish symptom profile baseline.
  - Determine patient has a diagnosis of IC.
  - Consider relaxation/stress management, pain management, and self-care behavioral modification.
  - Encourage patient to commit to learning about IC via ELMIRON® Patient Brochure.
  - Review IC Symptom Questionnaire or O’Leary-Sant IC Symptom and Problem Index, and to track their IC symptoms using the ELMIRON® Symptom Journal.
  - Make any recommended lifestyle changes.
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  - Take ELMIRON® as prescribed.

- **Continued Treatment**
  - Make any recommended lifestyle changes.
  - Take ELMIRON® as prescribed.

**PATIENT**

- **Encourage Patient to**
  - Commit to learning about IC via All About IC (allaboutic.com).
  - Interstitial Cystitis Association (icelp.org).
  - IC Network (ic-network.com).

- **Remind Patient to**
  - Continue taking ELMIRON® as prescribed.

- **MONTH 3 ON ELMIRON® FOLLOW-UP**
  - Patients receiving ELMIRON® should be reassessed after 3 months.
  - Review IC Symptom Questionnaire or O’Leary-Sant IC Symptom and Problem Index; assess results.
  - Review ELMIRON® Symptom Journal with patient.
  - Reframe symptom management strategies.
  - Stress adherence to ELMIRON® as prescribed.
  - Emphasize symptom improvement may be gradual.

- **MONTH 6 ON ELMIRON® FOLLOW-UP**
  - The clinical value and risks of continued ELMIRON® treatment in patients whose pain has not improved by 6 months is not known.
  - Review IC Symptom Questionnaire or O’Leary-Sant IC Symptom and Problem Index; assess results.
  - Review ELMIRON® Symptom Journal with patient.
  - If continuing ELMIRON® therapy, stress adherence to ELMIRON® as prescribed.

**INDICATION**

ELMIRON® is indicated for the relief of bladder pain or discomfort associated with interstitial cystitis.

**IMPORTANT SAFETY INFORMATION**

- **Contraindications**: ELMIRON® is contraindicated in patients with known hypersensitivity to the drug, structurally related compounds, or excipients.
- **Anticoagulant Activity**: ELMIRON® is a weak anticoagulant which may increase bleeding. Rectal hemorrhage was reported as an adverse event in 6.3% of patients. Patients undergoing invasive procedures or having signs/symptoms of underlying coagulopathy or other increased risk of bleeding (due to other therapies such as coumarin anticoagulants, heparin, t-PA, streptokinase, large dose aspirin, or nonsteroidal anti-inflammatory drugs) should be evaluated.
- **Alopecia**: In clinical trials of ELMIRON®, 97% of the cases of alopecia reported were alopecia areata, limited to a single area on the scalp.
- **Hepatic Insufficiency**: ELMIRON® has not been studied in patients with hepatic insufficiency. Because there is evidence of hepatic contribution to the elimination of ELMIRON®, hepatic impairment may have an impact on the pharmacokinetics of ELMIRON®. Caution should be exercised when using ELMIRON® in this patient population.
- **Information for Patients**: Patients should take the drug as prescribed, in the dosage prescribed, and no more frequently than prescribed. Patients should be reminded that ELMIRON® has a weak anticoagulant effect. This effect may increase bleeding times.
- **Pregnancy and Lactation**: Adequate and well-controlled studies have not been performed in pregnant women. Because animal studies are not always predictive of human response, this drug should be used in pregnancy only if clearly needed. It is not known if ELMIRON® is excreted in human milk. Caution should be exercised when ELMIRON® is administered to a nursing woman.
- **Most Common Adverse Reactions (frequency 1% to 4%)**: Alopecia (4%), diarrhea (4%), nausea (4%), headache (3%), rash (3%), dyspepsia (2%), abdominal pain (2%), liver function abnormalities (1%), and dizziness (1%).

Please see attached full Prescribing Information for ELMIRON®.

**REFERENCE**


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*Although patients with IC are likely to have higher Pelvic Pain and Urinary Frequency (PUFS) scores, the questionnaire cannot exclude other conditions with similar symptoms and is not sufficient to diagnose IC independent of medical history, physical examination, and appropriate diagnostic measures.