

# ELMIRON®

# PATIENT TREATMENT JOURNEY

ELMIRON®  
(pentosan polysulfate sodium) 100 mg Capsules

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



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<sup>1</sup>
- Determine patient is appropriate for ELMIRON® (pentosan polysulfate sodium) and start ELMIRON® therapy<sup>1-3</sup>
- Provide ELMIRON® Patient Starter Kit and Patient Brochure
- Consider manual physical therapy techniques by appropriately trained physicians<sup>1,2</sup>

PATIENT

## Encourage patient to<sup>2</sup>

- Commit to learning about IC via
  - All About IC ([allaboutic.com](http://allaboutic.com))
  - Interstitial Cystitis Association ([ichelp.org](http://ichelp.org))
  - National Institute of Diabetes and Digestive and Kidney Diseases ([niddk.nih.gov](http://niddk.nih.gov))
  - IC Network ([ic-network.com](http://ic-network.com))
- Take ELMIRON® as prescribed<sup>3</sup>
- Make any recommended lifestyle changes<sup>2</sup>
- Complete the IC Symptom Questionnaire or O'Leary-Sant IC Symptom and Problem Index, and to track their IC symptoms using the ELMIRON® Symptom Journal
- Be patient as symptom improvement may be gradual<sup>3</sup>
- Visit [orthoelmiron.com](http://orthoelmiron.com) for more information and to subscribe to the Journey to Relief® e-mail program

## MONTH 3 ON ELMIRON® FOLLOW-UP<sup>3</sup>

- Patients receiving ELMIRON® should be reassessed after 3 months. If improvement has not occurred and if limiting adverse events are not present, ELMIRON® may be continued for another 3 months<sup>3</sup>
- Review IC Symptom Questionnaire or O'Leary-Sant IC Symptom and Problem Index; assess results<sup>2,4,5</sup>
- Review ELMIRON® Symptom Journal with patient
- Reinforce symptom management strategies<sup>2</sup>
- Stress adherence to ELMIRON® as prescribed<sup>3</sup>
- Emphasize symptom improvement may be gradual<sup>3</sup>

## Remind patient to

- Continue taking ELMIRON® as prescribed<sup>3</sup>
- Refill ELMIRON® when necessary<sup>3</sup>
- Track their IC symptoms
- Understand that symptom improvement may be gradual<sup>3</sup>

## 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<sup>3</sup>
- Review IC Symptom Questionnaire or O'Leary-Sant IC Symptom and Problem Index; assess results<sup>2,4,5</sup>
- Review ELMIRON® Symptom Journal with patient
- If continuing ELMIRON® therapy, stress adherence to ELMIRON® as prescribed<sup>3</sup>

## In patients continuing therapy, ensure patients

- Continue taking ELMIRON® as prescribed<sup>3</sup>
- Refill ELMIRON® when necessary<sup>3</sup>
- Track their IC symptoms

## 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, high dose aspirin, or nonsteroidal anti-inflammatory drugs) should be evaluated for hemorrhage. Patients with diseases such as aneurysms,

thrombocytopenia, hemophilia, gastrointestinal ulcerations, polyps, or diverticula should be carefully evaluated before starting ELMIRON®.

- **Heparin-Induced Thrombocytopenia:** Caution should be exercised when using ELMIRON® in patients who have a history of heparin-induced thrombocytopenia.
- **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®.**

\*Although patients with IC are likely to have higher Pelvic Pain and Urgency/Frequency (PUF) 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.

References: 1. Hanno PM, Burks DA, Clemens JQ, et al. *American Urological Association (AUA) Guideline: Diagnosis and Treatment of Interstitial Cystitis/Bladder Pain Syndrome*. © 2014 American Urological Association Education and Research, Inc. <https://www.auanet.org/education/guidelines/ic-bladder-pain-syndrome.cfm>. Updated December 5, 2014. Accessed March 17, 2015. 2. Kahn BS, Stanford EJ, Mishell DR, Rosenberg MT, Wysocki S. Management of patients with interstitial cystitis or chronic pelvic pain of bladder origin: a consensus report. *Curr Med Res Opin*. 2005;21(4):509-516. 3. ELMIRON® [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. May 2018. 4. Parsons CL, Dell J, Stanford EJ, et al. Increased prevalence of interstitial cystitis: previously unrecognized urologic and gynecologic cases identified using a new symptom questionnaire and intravesical potassium sensitivity. *Urology*. 2002;60(4):573-578. 5. O'Leary MP, Sant GR, Fowler FJ, Whitmore KE, Spolarich-Kroll J. The interstitial cystitis symptom index and problem index. *Urology*. 1997;49(suppl 5A):58-63.

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