

ELMIRON[®]
(pentosan polysulfate sodium) 100 mg
Capsules

Starter Pack

Information about ELMIRON[®] for you and your patients

INDICATION

ELMIRON[®] is indicated for the relief of bladder pain or discomfort associated with interstitial cystitis (IC).

START THE CONVERSATION

SYMPTOM IMPROVEMENT MAY TAKE 3 TO 6 MONTHS¹

- Patients need to understand that symptom relief with ELMIRON[®] may be gradual. **Relief of bladder pain and discomfort associated with IC may take 3 to 6 months.**
- Patients should be informed that changes in vision should be reported and evaluated. Retinal examinations are suggested for all patients within 6 months of starting ELMIRON[®] and periodically thereafter.

COUNSEL PATIENTS TO ENCOURAGE ADHERENCE TO THERAPY

- Patients should take the drug as prescribed.
- 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. The clinical value and risks of continued treatment in patients whose pain has not improved by 6 months is not known.

DOSAGE & ADMINISTRATION

- The recommended dosage and administration of ELMIRON[®] is 100 mg orally 3 times daily with water 1 hour before or 2 hours after meals in patients ≥ 16 years.

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- ELMIRON[®] is contraindicated in patients with known hypersensitivity to the drug, structurally related compounds, or excipients.

WARNINGS

- **Retinal Pigmentary Changes:** Pigmentary changes in the retina, reported in the literature as pigmentary maculopathy, have been identified with long-term use of ELMIRON[®] (see ADVERSE REACTIONS). Although most of these cases occurred after 3 years of use or longer, cases have been seen with a shorter duration of use. While the etiology is unclear, cumulative dose appears to be a risk factor. Visual symptoms in the reported cases included difficulty reading, slow adjustment to low or reduced light environments, and blurred vision.

Please see additional Important Safety Information on back cover and enclosed full Prescribing Information for ELMIRON[®].



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EFFICACY

CLINICAL TRIALS

One Blinded, Placebo-Controlled Study

- In a one blinded, randomized, placebo-controlled study (N=151),¹ 38% (28/74) of patients taking ELMIRON® (pentosan polysulfate sodium) 300 mg/day reported at 3 months a greater than 50% improvement in bladder pain compared with 18% (13/74) of patients (all patients met the National Institutes of Health definition of IC) taking placebo (P=0.005). Clinical improvement in bladder pain was based upon patient's own assessment.¹

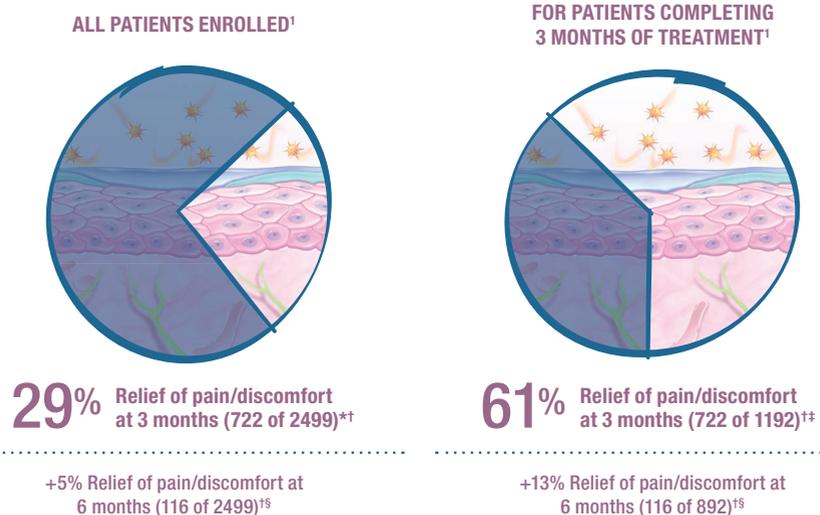
OPEN-LABEL STUDY—PHYSICIAN'S USAGE STUDY

Study Design

- Prospectively designed, open-label, retrospective analysis of 2499 patients who met the NIH definition of IC. Patients' pain/discomfort scores were evaluated every 3 months. Patients received ELMIRON® 300 mg/day without blinding.¹
- Study population:** The patients had a mean age of 47 years and 23% were over 60 years of age. Sixty percent of patients reported severe or unbearable pain at baseline.¹

RESULTS

SYMPTOM IMPROVEMENT AT 3 AND 6 MONTHS¹



*2499 patients received at least 1 dose of ELMIRON®.

†Pain scores that improved by 1 or 2 categories.

‡Number(%) of patients without pain/discomfort improvement at 3 months who had improvement at 6 months.

†1192 of 2499 patients received ELMIRON® treatment for 3 months. 52% of patients (1307) had dropped out or were ineligible for analysis.

‡Number(%) of patients without pain/discomfort improvement at 3 months who had improvement at 6 months.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS (continued)

- Retinal Pigmentary Changes (continued):** The visual consequences of these pigmentary changes are not fully characterized. Caution should be used in patients with retinal pigment changes from other causes in which examination findings may confound the appropriate diagnosis, follow-up, and treatment. Detailed ophthalmologic history should be obtained in all patients prior to starting treatment with ELMIRON®. If there is a family history of hereditary pattern dystrophy, genetic testing should be considered. For patients with preexisting ophthalmologic conditions, a comprehensive baseline retinal examination (including color fundoscopic photography, ocular coherence tomography (OCT), and autofluorescence imaging) is recommended prior to starting therapy. A baseline retinal examination (including OCT and autofluorescence imaging) is suggested for all patients within 6 months of initiating treatment and periodically while continuing treatment. If pigmentary changes in the retina develop, then risks and benefits of continuing treatment should be reevaluated, since these changes may be irreversible. Follow-up retinal examinations should be continued given that retinal and vision changes may progress even after cessation of treatment.

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patient handout

SAFETY PROFILE¹

Since there was not a control group of patients with interstitial cystitis who were concurrently evaluated, it is difficult to determine which events are associated with ELMIRON® and which events are associated with concurrent illness, medicine, or other factors.

Adverse Experience in Placebo-Controlled Clinical Trials of ELMIRON® 100 mg Three Times a Day for 3 Months¹

Body System/Adverse Experience	ELMIRON® n=128	Placebo n=130
Central Nervous System Overall Number of Patients*	3	5
Insomnia	1	0
Headache	1	3
Severe Emotional Lability/Depression	2	1
Nystagmus/Dizziness	1	1
Hyperkinesia	1	1
Gastrointestinal Overall Number of Patients*	7	7
Nausea	3	3
Diarrhea	3	6
Dyspepsia	1	0
Jaundice	0	1
Vomiting	0	2
Skin/Allergic Overall Number of Patients*	2	4
Rash	0	2
Pruritus	0	2
Lacrimation	1	1
Rhinitis	1	1
Increased Sweating	1	0
Other Overall Number of Patients*	1	3
Amenorrhea	0	1
Arthralgia	0	1
Vaginitis	1	1
Total Events	17	27
Total Number of Patients Reporting Adverse Events	13	19

*Within a body system, the individual events do not sum to equal overall number of patients because a patient may have more than one event.

PHARMACOLOGY

- Although the mechanism of action of ELMIRON® (pentosan polysulfate sodium) in patients with IC is not known, in preliminary clinical models, pentosan polysulfate sodium adhered to the bladder wall mucosal membrane.¹
- The drug may act as a buffer to control cell permeability, preventing irritating solutes in the urine from reaching the cells.¹ The clinical significance of the proposed mechanism of action has not been established.

SELECT IMPORTANT SAFETY INFORMATION

PRECAUTIONS

- 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.

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IMPORTANT SAFETY INFORMATION

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- **Information for Patients:** Patients should take the drug as prescribed, in the dosage prescribed, and no more frequently than prescribed. Patients should be informed that changes in vision should be reported and evaluated. Retinal examinations including optical coherence tomography (OCT) and autofluorescence imaging are suggested for all patients within 6 months of starting ELMIRON® and periodically during long-term treatment (see WARNINGS). Patients should be reminded that ELMIRON® has a weak anticoagulant effect. This effect may increase bleeding times.
- **Pregnancy and Nursing Mothers:** Adequate and well-controlled studies have not been performed in pregnant women. 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.
- **Pediatric Use:** Safety and effectiveness in pediatric patients below the age of 16 years have not been established.

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 read additional Important Safety Information on back cover and enclosed full Prescribing Information for ELMIRON®.

Reference: 1. ELMIRON® [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.

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