

## Patient Assessment Questionnaire

This questionnaire may help you and your doctor monitor your interstitial cystitis (IC) symptoms.

Before you begin treatment with ELMIRON<sup>®</sup> (pentosan polysulfate sodium), be sure to fill out the questionnaire below. Remember, ELMIRON<sup>®</sup> may have a gradual effect on symptoms—sometimes taking up to 3 months until noticeable improvement is seen. It's important to take ELMIRON<sup>®</sup> continuously as your doctor has prescribed. After 3 months of taking ELMIRON<sup>®</sup>, take the questionnaire again and use it in your conversations with your doctor. By reviewing your answers, you and your doctor will be able to track your progress.

### Instructions:

For each question below, please circle the answer that best describes how you feel. Then, mark your score (0-4) for each answer in the column on the right. When you are finished, add up the numbers in this column for your total score.

		0	1	2	3	4	START OF THERAPY MONTH 1 SCORE	MONTH 3 SCORE
1	How many times do you go to the bathroom during the day?	3-6	7-10	11-14	15-19	20+		
2	a. How many times do you go to the bathroom at night?	0	1	2	3	4+		
	b. If you get up at night to go to the bathroom, does it bother you?	Never	Mildly	Moderately	Severely			
3	Are you currently sexually active? <b>YES</b> _____ <b>NO</b> _____							
4	a. <b>IF YOU ARE SEXUALLY ACTIVE</b> , do you now or have you ever had pain or symptoms during or after sexual intercourse?	Never	Occasionally	Usually	Always			
	b. If you have pain, does it make you avoid sexual intercourse?	Never	Occasionally	Usually	Always			
5	Do you have pain associated with your bladder or in your pelvis (vagina, lower abdomen, urethra, perineum, testes, or scrotum)? <b>If you do not have pain, please skip question 6.</b>	Never	Occasionally	Usually	Always			
6	a. If you have pain, is it usually...	No Pain	Mild	Moderate	Severe			
	b. Does your pain bother you?	Never	Occasionally	Usually	Always			
7	Do you have urgency after going to the bathroom? <b>If you do not have urgency, please skip final question.</b>	Never	Occasionally	Usually	Always			
8	a. If you have urgency, is it usually...	No Urgency	Mild	Moderate	Severe			
	b. Does your urgency bother you?	Never	Occasionally	Usually	Always			
<b>TOTAL SCORE</b>								

© This is a modified version of the pelvic pain, urgency, and frequency (PUF) scale in the following article: (Parsons CL et al. *Urology*. 2002;60:573-578). 2000 C. Lowell Parsons, MD.

### WHAT IS ELMIRON<sup>®</sup> (pentosan polysulfate sodium)?

ELMIRON<sup>®</sup> is a prescription medicine used to treat bladder pain or discomfort associated with interstitial cystitis. It is not known if ELMIRON<sup>®</sup> is safe and effective in children under 16 years of age.

### IMPORTANT SAFETY INFORMATION

#### What is the most important information I should know about ELMIRON<sup>®</sup> (pentosan polysulfate sodium) Capsules?

Serious side effects have been reported with the use of ELMIRON<sup>®</sup>, including:

- **Changes in the retina of the eye (pigmentary maculopathy).** Taking ELMIRON<sup>®</sup> may be associated with pigment changes in the retina of the eye that may continue even after stopping treatment with ELMIRON<sup>®</sup>. Tell your healthcare provider including your eye doctor right away if you have any vision changes including any of these symptoms: difficulty reading, your vision takes longer to adjust to low or reduced light, and blurred vision

Throughout your treatment, regular eye examinations that include retinal examinations are suggested for early detection of retinal/macular changes. Your doctor will discuss with you when to get your first eye examination and follow up exams, and whether the treatment should be continued.

#### What are the possible side effects of ELMIRON<sup>®</sup>?

ELMIRON<sup>®</sup> may cause serious side effects including:

- changes in the retina of the eye
- increased bleeding

See **“What is the most important information I should know about ELMIRON<sup>®</sup> (pentosan polysulfate sodium) Capsules?”**

#### What are the most common side effects of ELMIRON<sup>®</sup>?

- The most common side effects are: hair loss, diarrhea, nausea, stomach pain, upset stomach, headache, rash, abnormal liver function tests, and dizziness

These are not all the possible side effects of ELMIRON<sup>®</sup>.

Call your doctor for medical advice about side effects. You are also encouraged to report side effects to the FDA: visit <http://www.fda.gov/medwatch> or call 1-800-FDA-1088. You may also report side effects to Janssen Pharmaceuticals, Inc. at 1-800-JANSSEN (1-800-526-7736).

#### How should I store ELMIRON<sup>®</sup>?

- Store ELMIRON<sup>®</sup> at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep ELMIRON<sup>®</sup> and all other medicines out of the reach of children.

#### How should I take ELMIRON<sup>®</sup>?

- Take ELMIRON<sup>®</sup> exactly as your healthcare provider tells you to take it.
- Take 1 capsule of ELMIRON<sup>®</sup> by mouth 3 times a day with water at least 1 hour before meals or 2 hours after meals. Each capsule contains 100 mg of ELMIRON<sup>®</sup>.
- If you take too much ELMIRON<sup>®</sup>, call your healthcare provider right away or go to the nearest emergency room.

Please see accompanying full Prescribing Information and read the Medication Guide or visit [www.orthoelmiron.com](http://www.orthoelmiron.com).

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