ELMIRON® is a prescription medication used to treat the bladder pain or discomfort associated with interstitial cystitis (IC). It is not known exactly how ELMIRON® works, but it is not a pain medication like aspirin or acetaminophen and therefore must be taken continuously for relief as prescribed by your doctor.

**Important Safety Information**

What is the most important information I should know about ELMIRON® (pentosan polysulfate sodium) Capsules?

You must take ELMIRON® as prescribed by your doctor in the dosage prescribed but no more frequently than prescribed. ELMIRON® is a weak anticoagulant (blood thinner) which may increase bleeding. Call your doctor if you will be undergoing surgery or will begin taking anticoagulant therapy such as warfarin sodium, heparin, high doses of aspirin, or anti-inflammatory drugs such as ibuprofen.

Who should not take ELMIRON®?

- Patients undergoing surgery should speak with their doctor about when to discontinue ELMIRON® prior to surgery.
- ELMIRON® should be used during pregnancy only if clearly needed.

What does your doctor need to know?

- If you are taking anticoagulant therapy such as warfarin sodium, heparin, high doses of aspirin, or anti-inflammatory drugs such as ibuprofen.
- If you are pregnant.
- If you have any liver problems.

What should I avoid while taking ELMIRON®?

Anticoagulant therapy such as warfarin sodium, heparin, high doses of aspirin, or anti-inflammatory drugs such as ibuprofen until you speak with your doctor.

What should I do if I forget to take my ELMIRON®?

Take ELMIRON® exactly as prescribed. If you miss a dose, take it as soon as you remember, but you may need to take it at a different time of day. If you miss 2 doses in a row, call your doctor. Do not take 2 doses at the same time.

**Instructions**

For each question below, please circle the answer that best describes how you feel. Then, mark your score (0 to 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.

### Patient Assessment Questionnaire

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

Before you begin treatment with ELMIRON® (pentosan polysulfate sodium), be sure to fill out the questionnaire below. Remember, ELMIRON® may have a gradual effect on symptoms—sometimes taking up to 3 months until noticeable improvement is seen. It’s important to take ELMIRON® continuously as your doctor has prescribed. After 3 months of taking ELMIRON®, 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 to 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.

<table>
<thead>
<tr>
<th>Question</th>
<th>Score Options</th>
<th>Start of Therapy Score</th>
<th>Month 3 Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>How many times do you go to the bathroom during the day?</td>
<td>0-6</td>
<td>1-10</td>
<td>11-15</td>
</tr>
<tr>
<td>If you get up at night to go to the bathroom, does it bother you?</td>
<td>Never, Mildly</td>
<td>Moderately</td>
<td>Severely</td>
</tr>
<tr>
<td>Are you currently sexually active?</td>
<td>Yes, No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are you sexually active?</td>
<td>Yes, No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If you have pain, does it make you avoid sexual intercourse?</td>
<td>Never, Occasionally</td>
<td>Usually</td>
<td>Always</td>
</tr>
<tr>
<td>Do you have pain associated with your bladder or in your pelvis?</td>
<td>Never, Occasionally</td>
<td>Usually</td>
<td>Always</td>
</tr>
<tr>
<td>If you do not have pain, please skip question 6.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How many times do you go to the bathroom at night?</td>
<td>0, 1, 2, 3, 4+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If you get up at night to go to the bathroom, does it bother you?</td>
<td>Never, Mildly</td>
<td>Moderately</td>
<td>Severely</td>
</tr>
<tr>
<td>Do you have pain, is it usually...</td>
<td>No, Mild, Moderate, Severe</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your pain bother you?</td>
<td>Never, Occasionally</td>
<td>Usually</td>
<td>Always</td>
</tr>
<tr>
<td>Do you have urgency after going to the bathroom?</td>
<td>Never, Occasionally</td>
<td>Usually</td>
<td>Always</td>
</tr>
<tr>
<td>If you do not have urgency, please skip final question.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have urgency, is it usually...</td>
<td>No, Mild, Moderate, Severe</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your urgency bother you?</td>
<td>Never, Occasionally</td>
<td>Usually</td>
<td>Always</td>
</tr>
</tbody>
</table>

© 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.

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What are the most common side effects of ELMIRON®?

The most common side effects are hair loss, diarrhea, nausea, blood in the stool, headache, rash, upset stomach, abnormal liver function tests, dizziness, and bruising. Weight gain and swelling caused by fluid buildup in the body have also been reported in patients taking ELMIRON®. Call your doctor if these side effects persist or are bothersome or if there is blood in your stool or if you have any other side effect that bothers you or that does not go away.

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).

Please click here to read the full Prescribing Information for ELMIRON®.

www.orthoelmiron.com

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