Interstitial cystitis (IC) and ELMIRON® (pentosan polysulfate sodium) treatment

What is IC?
IC is a chronic, yet manageable, bladder condition, characterized by bladder or pelvic pain, pain during or after sexual intercourse, and urinary urgency and frequency.

What is ELMIRON®?
ELMIRON® is a prescription medication used to treat the bladder pain or discomfort associated with 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.

The ELMIRON® EarlyAssist™ Co-Pay Support Program
- With EarlyAssist™, commercially eligible patients PAY AS LITTLE AS $5 per month – for up to 4 months of ELMIRON®
- Not valid for patients enrolled in Medicare, Medicare Part D, Medicaid, or other government-funded programs
- Visit https://www.orthoelmiron.com/patient/elmiron-savings-assistance for full eligibility requirements

How ELMIRON® may relieve IC pain
IC may be caused by a breakdown of the protective lining of the bladder, which may allow irritating substances in the urine to aggravate and inflame the bladder wall, resulting in pain.

While the precise way ELMIRON® works is not fully understood, ELMIRON® is thought to adhere to the bladder mucosal lining, preventing potentially irritating substances in the urine from reaching the bladder wall.

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 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).

It is very important that you take ELMIRON® (pentosan polysulfate sodium) as directed and stick with it

Symptom improvement is generally gradual

- Symptom relief may take 3 to 6 months
- You should take 1 capsule of ELMIRON® by mouth 3 times a day, with water, at least 1 hour before or 2 hours after meals. Each capsule contains 100 mg of ELMIRON®
- You should continue to take ELMIRON® until otherwise instructed by your healthcare professional
- Do not stop taking ELMIRON® or reduce your dosage just because you are feeling better or because you think ELMIRON® may not be working right away. You should take ELMIRON® until otherwise instructed by your healthcare professional
- While taking ELMIRON®, avoid anticoagulant therapy, such as warfarin sodium, heparin, high doses of aspirin or high doses of anti-inflammatory drugs, such as ibuprofen, until speaking with your healthcare professional
- Schedule regular follow-up visits with your healthcare professional such as monthly visits for the first few months after starting ELMIRON®

Lifestyle modifications you can make to help manage symptoms

- **Dietary modifications:** Avoid foods or beverages that may provoke symptoms (e.g., coffee, tea, spicy foods, chocolate)
- **Stress reduction:** Try controlled breathing exercises, and applying warm or cold compresses on the lower abdomen
- **Physical therapy:** Gentle stretching and pelvic floor muscle-relaxation exercises
- **Gentle exercise:** Walking, yoga, and low-impact aerobics may be beneficial
- **Bladder training:** Practice scheduled voiding patterns

- Additional resources, such as IC-friendly diet tips, and stress and coping techniques, are available through the following:
  - [www.orthoelmiron.com](http://www.orthoelmiron.com): A Janssen Pharmaceuticals, Inc., website offering information on IC and ELMIRON® to patients
  - [Journey to Relief®](http://www.ichelp.org): A free e-mail support program that provides you with great tips, resources, and money-saving offers
  - [Interstitial Cystitis Association](http://www.ichelp.org): A national, nonprofit organization offering information and support to IC patients and their families

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[Please click here for full Product Information for ELMIRON® on www.orthoelmiron.com](http://www.orthoelmiron.com).