

ELMIRON® is the only oral medicine FDA-approved to treat the bladder pain or discomfort of interstitial cystitis (IC)¹



A GUIDE TO HELP MANAGE IC AND STAY ON TRACK WITH TREATMENT

IMPORTANT SAFETY INFORMATION

WHAT IS ELMIRON® (pentosan polysulfate sodium)?

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

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

Serious side effects have been reported with the use of ELMIRON®, including:

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

ELMIRON® (pentosan polysulfate sodium) Can Help Treat IC-Related Pain

LIVING WITH IC

Interstitial cystitis is a condition associated with pain or discomfort in the bladder or pelvic area that keeps coming back.²

Symptoms may vary from person to person and can change over time.²

SYMPTOMS^{2,3}:



Pelvic or abdominal pain



Frequent urination (including at night)



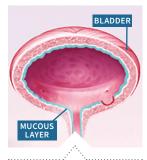
Urge to urinate even after emptying the bladder



Pain or discomfort during or after sex

Occasionally, symptoms may "flare up" or intensify for several hours, days, or weeks.⁴

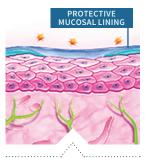
HOW ELMIRON® MAY WORK



IC may be caused by damage to the protective lining of the bladder^{3,5}



Irritating substances may inflame the exposed bladder wall^{3,5}



ELMIRON® adheres to the bladder wall to buffer against irritating substances¹

IC, interstitial cystitis.

IMPORTANT SAFETY INFORMATION (continued)

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

- Increased bleeding. ELMIRON® may increase bleeding. Tell your healthcare provider right away if you have any of these symptoms:
 - bruising easily
 - o nosebleeds
 - o bleeding gums
 - o blood in your stool

Your risk of bleeding may be increased if you take ELMIRON® along with other medicines such as:

- o warfarin sodium
- high doses of aspirin
- heparin
- o anti-inflammatory medicines such as ibuprofen

Tell your healthcare provider if you are taking any of these medicines.





It may take up to 3-6 months to see results.

ALWAYS TAKE ELMIRON® AS PRESCRIBED1

The recommended dosage of ELMIRON® is:



1 pill 3 times daily

Take ELMIRON® with water at least:



1 hour before meals or 2 hours after meals



Follow any other advice your doctor gives you for managing symptoms—for example, avoiding foods that may make your symptoms worse

TRACK SYMPTOMS AND SIDE EFFECTS

- ✓ Tell your doctor if you experience any side effects
- Record the frequency and severity of symptoms and note any foods that cause flare-ups, so you can discuss your progress with your doctor

REMEMBER YOUR REFILLS

START DATE:	MY DOSE IS:
Date of Refill 1:	Date of Refill 4:
Date of Refill 2:	Date of Refill 5:
Date of Refill 3:	Date of Refill 6:

IMPORTANT SAFETY INFORMATION (continued)

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

Tell your healthcare provider if you are going to have surgery. Your healthcare provider may stop ELMIRON® before you have surgery.

Talk to your healthcare provider about when to stop taking ELMIRON® and when to start taking it again.

Watch Your Diet^{2,5-7*}

Avoiding foods known to be common bladder irritants may help control IC symptoms and flare-ups. See examples of IC-friendly foods and foods to avoid below.



FRUITS

IC Friendly: Bananas; blueberries; pears; honeydew melons; raisins; nontart apples; watermelons; pumpkins Avoid: Citrus fruits; pineapples; kiwis; tart apples (Granny Smith); tart or bitter grapes; and sour berries



VEGETABLES

IC Friendly: Most vegetables, including leafy greens and root vegetables (eg, potatoes, carrots)

Avoid: Raw onions; hot chili peppers; pickles; sauerkraut; tomato products; edamame; and roasted soybeans



MILK/DAIRY

IC Friendly: Milk; cottage cheese, mozzarella, mild cheddar, feta, ricotta, and string cheeses Avoid: Yogurt; processed and heavily spiced cheeses; and chocolate ice cream



CARBOHYDRATES/GRAINS

IC Friendly: Minimally processed pastas, breads, and grains (eg, quinoa, oats, grits, couscous) [except those listed at the right]

Avoid: Heavily processed or fortified breads and pastas; heavily preserved, sweetened, flavored and chocolate cereals; and soy flour



MEATS/FISH

IC Friendly: Unprocessed meats and fish; and deli meats (glutenand color-free)

Avoid: Deli meats (spiced/salted, eg, salami); aged, canned, cured, processed, prepackaged, or smoked meats/fish



BEVERAGES

IC Friendly: Water; milk; almond milk; non-acidic juices (eg, pear); and chamomile, peppermint, and herbal teas Avoid: Alcoholic beverages; coffee and tea; carbonated drinks (eg, soda); citrus and acidic juices (eg, cranberry)



NUTS/OILS

IC Friendly: Almonds; cashews; peanuts; and most oils

Avoid: Filberts; hazelnuts; pecans; and pistachios



SEASONINGS

Avoid: Ketchup; spicy mustard; miso; soy sauce; vinegar; cayenne; hot curry powder; horseradish; and spicy foods



FOOD ADDITIVES

Avoid: Ascorbic acid; monosodium glutamate (MSG); aspartame (NutraSweet®1); saccharin; and foods containing preservatives and/or artificial ingredients/colors

Adopt Helpful Habits^{2,4}

There are also some lifestyle changes that you can make to help manage your IC symptoms:

Apply warm or cold compresses on the lower abdomen

Try **gentle exercise** such as walking, yoga, or low-impact aerobics

Use stress-reduction techniques like controlled breathing exercises

Try **bladder retraining** (lengthening the time between bathroom visits)

IC, interstitial cystitis.

^{*}This is not an all-inclusive list of foods and beverages that are IC friendly or that should be avoided.

[†]NutraSweet is a registered trademark of NutraSweet Property Holdings, Inc.

PAY AS LITTLE AS \$25 PER FILL

Our Co-Pay Support Program



To obtain the savings coupon and for full eligibility requirements, visit **orthoelmiron.com/coupon** or scan the QR code with your phone.

PATIENTS WITH COMMERCIAL INSURANCE:

Eligible patients using commercial or private insurance can save on out-of-pocket costs for ELMIRON® (pentosan polysulfate sodium). Eligible patients pay as little as \$25 per fill. There is a limit to savings per fill and a maximum program benefit per calendar year. Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their medicines. Terms expire at the end of each calendar year. Offer subject to change or end without notice. Restrictions, including monthly maximums, may apply.

There is no income requirement. See program requirements at OrthoElmiron.com/coupon.

PATIENTS WITHOUT COMMERCIAL INSURANCE:

If you don't have prescription drug coverage, find out more about assistance programs that could provide discounted or free prescriptions at <u>JNJwithMe.com</u>.

IMPORTANT SAFETY INFORMATION

What should I tell my healthcare provider before taking ELMIRON®?

Tell your healthcare provider if you:

- have a personal or family history of eye problems of the retina
- have a history of aneurysms
- have problems with easy bleeding (thrombocytopenia)
- have hemophilia
- have gastrointestinal problems such as ulcerations, polyps, or diverticula
- have any liver problems
- are pregnant or plan to become pregnant. ELMIRON® should be used during pregnancy only if clearly needed. Tell your healthcare provider if you become pregnant while taking ELMIRON®. You and your healthcare provider should decide if you should continue to take ELMIRON®
- are breastfeeding or plan to breastfeed. It is not known if ELMIRON® passes into your breastmilk. You and your healthcare provider should decide if you will take ELMIRON® or breastfeed
- Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements

IMPORTANT SAFETY INFORMATION (continued)

What are the possible side effects of ELMIRON®?

ELMIRON® 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® (pentosan polysulfate sodium) Capsules?"

The most common side effects of ELMIRON® are:

- hair loss
- diarrhea
- nausea
- · stomach pain
- upset stomach
- headache
- rash
- abnormal liver function tests
- dizziness

These are not all the possible side effects of ELMIRON®.

Call your doctor for medical advice about side effects. You are also encouraged to report side effects to the FDA: visit https://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®?

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

How should I take ELMIRON®?

- Take ELMIRON® exactly as your healthcare provider tells you to take it.
- Take 1 capsule of ELMIRON® 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®.
- If you take too much ELMIRON®, call your healthcare provider right away or go to the nearest emergency room.

Please read the full <u>Prescribing Information</u> and <u>Medication Guide</u> for ELMIRON® and discuss any questions you have with your doctor.

References: 1. ELMIRON® [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. July 2024.
2. Interstitial cystitis/painful bladder syndrome. U.S. Department of Health and Human Services. Accessed October 28, 2024. https://www.niddk.nih.gov/health-information/urologic-diseases/interstitial-cystitis-painful-bladder-syndrome 3. Butrick CW. Patients with chronic pelvic pain: endometriosis or interstitial cystitis/painful bladder-syndrome? *J Soc Laparoendosco Surg*. 2007;11(2):182-189. 4. Hanno PM, Erickson D, Moldwin R, Faraday MM; American Urological Association. Diagnosis and treatment of interstitial cystitis/bladder pain syndrome: AUA guideline amendment. *J Urol*. 2015;193(5):1545-1553. 5. Metts JF. Interstitial cystitis: urgency and frequency syndrome. *Am Fam Physician*. 2001;64(7):1199-1206. 6. Friedlander JI, Shorter B, Moldwin RM. Diet and its role in interstitial cystitis/bladder pain syndrome (IC/BPS) and comorbid conditions. *BJU Int*. 2012; 109(11):1584-1591. 7. 2012 ICN Food List. ICNetwork. Accessed October 28, 2024. https://www.ic-network.com/downloads/2012icnfoodlist.pdf

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