



A Patient's Guide to Elmiron

Eye Damage, New Warning and
Current Lawsuit Information



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From this guide,
you will learn:

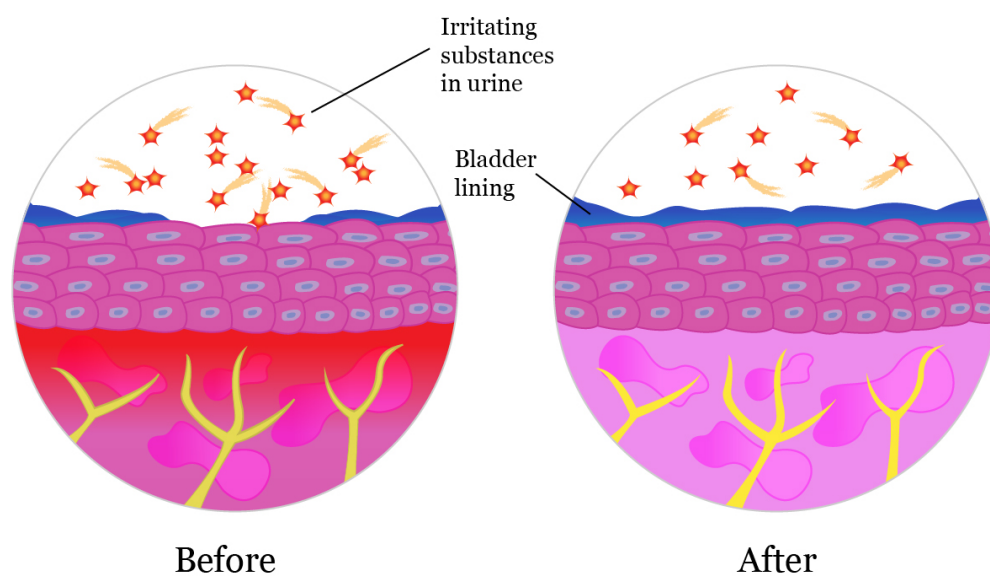
- How Elmiron may cause vision damage
- If Elmiron has been recalled
- Who is eligible to file an Elmiron lawsuit

What Is Elmiron?

If you are one of millions of Americans affected by a painful bladder condition called interstitial cystitis, you may have taken Elmiron, also known as pentosan polysulfate sodium. It doesn't cure IC, but it may help relieve symptoms by protecting the bladder wall from irritants.

Elmiron is the only oral medication approved by the FDA to treat IC pain and discomfort. According to insurance data gathered by eye doctors, hundreds of thousands of people may have used the drug since its approval in 1996.

How Elmiron Works



Most Elmiron side effects are mild, but recent studies suggest the drug may lead to eye damage called pigmentary maculopathy.

4M to 12M Americans

are affected by interstitial cystitis: 1 million to 4 million men and 3 million to 8 million women

Nearly 200 Lawsuits

in New Jersey federal court claim Elmiron caused permanent eye damage; attorneys expect hundreds more will be filed

24 Years

elapsed before Janssen Pharmaceuticals added a warning for pigmentary maculopathy to Elmiron's drug label

Elmiron and Vision Damage

Since 2018, eye doctors have published several studies showing that chronic Elmiron exposure may cause retinal damage. This leads to a unique eye injury called pigmentary maculopathy.

Damage may get worse even after patients stop taking Elmiron. Researchers say thousands of Elmiron patients who haven't been screened for eye damage may be at risk.

In June 2020, Janssen Pharmaceuticals added a warning for pigmentary maculopathy to Elmiron's label.

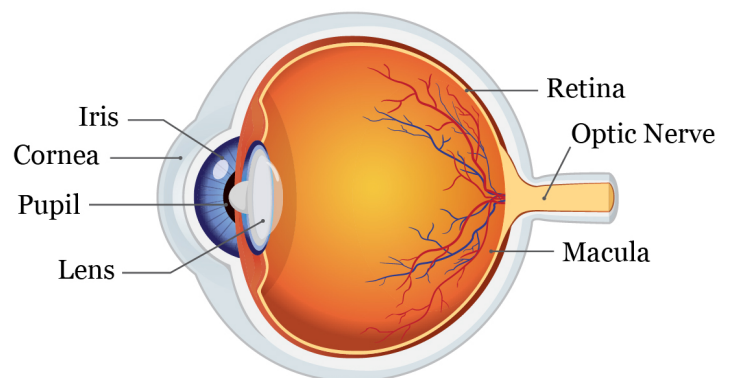
“Our subsequent investigations demonstrated that this unique maculopathy is strongly associated with chronic [pentosan polysulfate sodium] exposure, not IC itself or its other therapies. In fact, this characteristic maculopathy has, to date, been exclusively diagnosed in patients reporting prior PPS exposure.”

— Drs. Adam M. Hanif and Nieraj Jain, Review of Ophthalmology

Elmiron eye damage symptoms in studies include:

- Areas of vision loss
- Difficulty adjusting to dim lighting or the dark
- Difficulty reading
- Difficulty seeing objects that are close
- Dim vision

Anatomy of an Eye



How Soon Can Vision Problems Occur?

Vision problems can occur any time after three years of Elmiron use, according to Drs. Adam M. Hanif and Nieraj Jain. These visual problems may last for years, and some may be permanent.

Has Elmiron Been Recalled?

Despite growing evidence of eye damage linked to Elmiron, Janssen Pharmaceuticals hasn't announced a recall. The FDA has not requested a recall or issued a safety communication about vision problems associated with the drug.

Even though Elmiron has been on the market since 1996, Janssen Pharmaceuticals only recently added a warning to the drug's label.

“Only as recently as June 16, 2020, did Janssen change the label to include a warning for people using Elmiron for three years or longer possibly being afflicted with pigmentary maculopathy.”

— Trent B. Miracle, attorney and head of the Pharmaceutical Litigation Group at Simmons Hanly Conroy

Should I Continue Taking Elmiron?

The FDA hasn't released any recommendations for stopping Elmiron treatment.

Dr. Robin A. Vora recommends patients without vision symptoms get screened for retina damage at least once a year. People who show signs of damage should speak to their doctor about stopping treatment.

Elmiron Alternatives

Elmiron is the only oral drug approved to treat IC, but a few treatment alternatives may help manage IC symptoms.

- Diet and exercise
- Bowel training to help IC symptoms
- Bladder training to help with urinary urgency and pain
- Physical therapy for muscle spasms
- Pain relievers to control IC pain
- Using a catheter or syringe to inject dimethyl sulfoxide into the bladder

Why Are People Filing Lawsuits?

Hundreds of people have already filed Elmiron lawsuits to hold Janssen Pharmaceuticals accountable for exposing them to the risk of pigmentary maculopathy and other eye problems.

Lawsuits claim that Elmiron's makers knew or should have known that the drug could damage the eye, and they didn't warn the public until June 2020.

“The actions involve common factual issues concerning the propensity of Elmiron to cause retinal injuries, notably atypical or pigmentary maculopathy.”

— United States Judicial Panel on Multidistrict Litigation

Can I File an Elmiron Lawsuit?

If you or a loved one took Elmiron for at least two years and were diagnosed with vision problems, you may qualify to file a lawsuit for compensation. Vision problems and diagnosis must have occurred on or after Jan. 1, 2010.

A lawyer can review your case for free and help gather medical records to build a case.

You may qualify to file an Elmiron lawsuit if you or a loved one:

- Have been diagnosed with pigmentary maculopathy, retinal maculopathy or macular degeneration
- Received a diagnosis within one year of stopping Elmiron treatment
- Experienced blurred vision, difficulty reading, distorted vision, eye pain, issues adjusting to darkness, vision disturbances or vision loss
- Sought treatment for vision issues



Questions Your Elmiron Lawyer Might Ask

What condition have you been diagnosed with?

Typically, people filing Elmiron lawsuits have received a diagnosis of vision problems such as maculopathy (pigmentary or retinal) and macular degeneration. Medical records will help verify the diagnosis.

When did the vision changes start?

Try to recall when you started having vision problems. Generally, people filing lawsuits started having problems after taking Elmiron for at least two years or within one year of stopping.

How did your vision problems affect your life?

Make sure you tell your attorney how your vision problems impacted your life. Have daily activities become more difficult? Have you suffered emotionally because of these problems? Be open and honest.

How long did you take Elmiron?

The length of time you took Elmiron is important to your potential case. Most people filing lawsuits have taken Elmiron for at least two years.

Do you have a history of eye problems?

It's important to be honest with your attorney if you have a history of eye problems. If you have medical records, have them handy.

What treatments have you been using for vision problems?

Tell your attorney about any drugs or other therapies prescribed by your medical provider for vision problems. He or she will want to know if they are helping.

What's your prognosis?

Make sure you are ready to discuss everything your medical provider told you about how your vision problems will affect you long term and if you will recover your vision.

Patient Checklist

Items to Have Ready for Your Free Consultation



Medical Records, Eye Medications & Treatments



Notes About How Vision Loss Affects Your Life



Record of Elmiron Use (Medical Records, Receipts)

Sources

1. American Academy of Ophthalmology. (2019, October 12). More Evidence Linking Common Bladder Medication to a Vision-threatening Eye Condition. Retrieved from <https://www.aaopt.org/newsroom/news-releases/detail/evidence-linking-bladder-medication-eye-condition>
2. Foote, J., Hanif, A. & Jain, N. (2019, April 1). MP47-03 Chronic Exposure To Pentosan Polysulfate Sodium Is Associated With Retinal Pigmentary Changes And Vision Loss. Retrieved from <https://www.auajournals.org/doi/10.1097/01.JU.0000556315.46806.ca>
3. Hanif, A.M. & Jain, N. (2019, July 10). Clinical Pearls for a New Condition: Pentosan polysulfate therapy, a common treatment for interstitial cystitis, has been associated with a maculopathy. Retrieved from <https://www.reviewofophthalmology.com/article/clinical-pearls-for-a-new-condition>
4. Huckfeldt, R.M. & Vavvas, D.G. (2019, November 6). Progressive Maculopathy After Discontinuation of Pentosan Polysulfate Sodium. Retrieved from <https://www.healio.com/ophthalmology/journals/osli/2019-10-50-10/%7B324bde2e-2389-4815-bf5e-fe3b2eb18062%7D/progressive-maculopathy-after-discontinuation-of-pentosan-polysulfate-sodium>
5. Jain, N. et al. (2019, November 6). Association of macular disease with long-term use of pentosan polysulfate sodium: findings from a US cohort. Retrieved from <https://bjo.bmj.com/content/early/2019/11/06/bjophthalmol-2019-314765>
6. National Institute of Diabetes and Digestive and Kidney Diseases. (n.d.). Definition & Facts of Interstitial Cystitis. Retrieved from <https://www.niddk.nih.gov/health-information/urologic-diseases/interstitial-cystitis-painful-bladder-syndrome/definition-facts>
7. Pearce, W.A., Chen, R. & Jain, N. (2018). Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate Sodium. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/29801663>
8. Pelczar vs. Teva Branded Pharmaceutical Products R&D et al. (2020, March 26). United States District Court District Of Connecticut. Complaint. Case 3:20-cv-00406. Retrieved from <https://aboutlawsuits-wpengine.netdna-ssl.com/wp-content/uploads/2020-03-26-Complaint.pdf>
9. U.S. Food and Drug Administration. (2020, June). Elmiron Prescribing Information. Retrieved from https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/020193s014lbl.pdf
10. United States Judicial Panel on Multidistrict Litigation. (2020, December 15). IN RE: Elmiron (Pentosan Polysulfate Sodium) Products Liability Litigation, Transfer Order. Retrieved from <https://www.jpml.uscourts.gov/sites/jpml/files/MDL-2973-Transfer%20Order-12-20.pdf>
11. United States Judicial Panel on Multidistrict Litigation. (2021, February 17). MDL Statistics Report - Distribution of Pending MDL Dockets by District. Retrieved from https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-February-17-2021.pdf
12. Vora, R.A., Patel, A.P. & Melles, R. (2020, January). Prevalence of Maculopathy Associated with Long-Term Pentosan Polysulfate Therapy. Retrieved from [https://www.aaojournal.org/article/S0161-6420\(20\)30040-3/abstract](https://www.aaojournal.org/article/S0161-6420(20)30040-3/abstract)

Contributors

Michelle Llamas

Senior Writer, Drugwatch

Michelle Llamas is a member of the American Medical Writers Association and a former legal assistant for plaintiff's injury law firms.

Sophia Clifton

Editor, Drugwatch

Sophia Clifton holds a Bachelor of Arts in English and five health literacy certificates from the Centers for Disease Control and Prevention.

Trent B. Miracle, Esquire

Reviewer, Trial Attorney and Pharmaceutical Litigation Expert

Trent B. Miracle leads the Pharmaceutical Litigation Group at Simmons Hanly Conroy and has helped secure nearly \$360 million in settlements on behalf of clients harmed by pharmaceutical drugs.