

Pentosan – pigmentary maculopathy (changes in the retina of the eye) risk of pigmentary maculopathy (changes in the retina of the eye), especially after long-term use

[EDA performs label update to include the following:](#)

Warnings and precautions

Rare cases of retinal disorders (pigmentary maculopathy) have been reported with use of elmiron (especially after long term use). Tell your doctor immediately if you experience visual changes such as difficulty when reading, visual distortions, altered colour vision and/or slower adjustment to low or reduced light. Your doctor will discuss with you whether the

treatment should be continued. For early detection of retinal disorders, eye examination will be performed regularly

Pentosan polysulfate sodium is used to treat bladder pain syndrome (interstitial cystitis) and is marketed in Australia under the brand name Elmiron. People may take the medicine for many years for ongoing relief of symptoms associated with the syndrome.

There are reports in overseas medical literature of rare cases of pigmentary maculopathy, which can lead to visual changes, associated with use of pentosan polysulfate sodium, especially after long-term therapy. In Australia, the Therapeutic Goods Administration has not received any adverse event reports for maculopathy or visual disorders in patients using pentosan polysulfate

Post-Marketing Experience

The following adverse reactions have been identified during post approval use of pentosane polysulfate sodium; because these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure:

- pigmentary changes in the retina

References: TGA ([Click here](#))