

Direct Healthcare Professional Communication

12.07.2019

Elmiron (pentosan polysulfate sodium): risk of pigmentary maculopathy

Dear Healthcare professional,

bene-Arzneimittel GmbH in agreement with the European Medicines Agency and the Health Products Regulatory Authority (HPRA) would like to inform you of the following:

Summary

- **Pigmentary maculopathy has been reported rarely, with pentosan polysulfate sodium, especially after long-term use**
- **During treatment, patients should have regular ophthalmic examination for early detection of pigmentary maculopathy, particularly those taking pentosan polysulfate sodium long-term**
- **Patients should be advised to promptly seek medical advice in case of visual changes such as reading difficulty and slow adjustment to low or reduced light environments**

Background on the safety concern

Elmiron is indicated for the treatment of bladder pain syndrome characterised by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition.

Cases of pigmentary maculopathy have been described in the literature after use of pentosan polysulfate sodium in patients with a diagnosis of interstitial cystitis also known as bladder pain syndrome.^{1,2} In most cases this was after long-term use and with a dosage exceeding the recommended dosage of 100 mg orally three times a day.

The pigmentary maculopathy described differs from other forms: fundus examination showed unique subtle paracentral hyperpigmentation at the level of the retinal pigment epithelium (RPE) with associated areas of RPE atrophy; multimodal retinal imaging demonstrated abnormalities of the RPE and overlying retina generally contained in multiple well-delineated areas¹. This unique maculopathy was only observed with use of pentosan polysulfate sodium.

The pathogenesis for pigmentary maculopathy with pentosan polysulfate sodium is currently unclear and it is unknown whether drug cessation will halt or alter the course of this retinal disorder. Nevertheless, as a precautionary measure, treatment cessation should be considered in affected patients.

Given the seriousness and potentially irreversible nature of the pigmentary maculopathy, all patients should have regular ophthalmological examinations, particularly patients taking pentosan polysulfate sodium long-term. This monitoring may allow early detection of pigmentary maculopathy, potentially at a reversible stage.

The product information will be updated to include these warnings.

1. Pearce WA, Chen R, Jain N. Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate Sodium, *Ophthalmology* (2018); 125(11): 1793-1802.
2. Foote J, Hanif A, Jain N, Atlanta, GA. MP47-03 - Chronic Exposure to Pentosan Polysulfate Sodium is Associated with Retinal Pigmentary Changes and Vision Loss. *J. Urol.* (2019); 201, No. 4S, Supplement, Sunday

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 676 4971; Fax: +353 1 676 2517; Website: www.hpra.ie; Email: medsafety@hpra.ie.

Company contact point

If you have further questions or require additional information, please contact medservice@bene-gmbh.de or at +49 (0) 89 74987-0.



Dr. Constanze Waltenberger
Medical Director
bene-Arzneimittel GmbH



Dr. Stefanie Staack
EU-QPPV
bene-Arzneimittel GmbH
