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Direct Healthcare Professional Communication

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Elmiron (pentosan polysulfate sodium): risk of pigmentary maculopathy

Dear Healthcare professional,

Bene-Arzneimittel GmbH (Marketing Authorisation Holder) and Consilient Health Limited (Distributor in the UK), in agreement with the European Medicines Agency and the Medicines and Healthcare products Regulatory Agency (MHRA) 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 (particularly those taking pentosan polysulfate sodium long-term) should have regular ophthalmic examination for early detection of pigmentary maculopathy**
- **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

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*

and overlying retina generally contained in multiple well-delineated areas[1]. 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 taking pentosan polysulfate sodium (particularly those taking it long-term) should have regular ophthalmological examinations. This monitoring may allow early detection of pigmentary maculopathy, potentially at a reversible stage.

The product information will be updated to include these warnings.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the MHRA through the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Alternatively, prepaid Yellow Cards for reporting are available by writing to FREEPOST YELLOW CARD (no other address details necessary); by emailing yellowcard@mhra.gov.uk; at the back of the British National Formulary (BNF); by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789; or by downloading and printing a form from the Yellow Card website.

Adverse events may also be reported to the company (see contact details below).

Company contact point

If you have further questions or require additional information, please contact the Medical Information Department at Consilient Health Limited on +44 (0) 203 751 1888 (option 1) or email drugsafety@consilienthealth.com.

Yours faithfully,

Anne Fairey

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Chief Medical Officer
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