Elmiron® (pentosan polysulfate sodium)

The purpose of this letter is to inform you of an important safety update relating to ELMIRON® capsules, which is indicated for the relief of bladder pain or discomfort associated with interstitial cystitis (IC).1

A new WARNING for **pigmentary changes in the retina**, reported in the literature as **pigmentary maculopathy**, has been added to the ELMIRON® United States Prescribing Information (USPI) June 2020.1

Cases of pigmentary changes have been reported with long-term use of ELMIRON®. Although most of these cases occurred after **3 years of use or longer**, cases have been seen with a shorter duration of use. While the etiology is unclear, **cumulative dose** appears to be a risk factor. Visual symptoms in the reported cases included **difficulty reading**, **slow adjustment to low or reduced light environments**, and **blurred vision**. These **changes may be irreversible**, and retinal and **vision changes may progress even after cessation of therapy**.2-5

The ELMIRON® USPI is being updated to include a new WARNING for Retinal Pigmentary Changes (included below) and to add additional information about retinal pigmentary changes in the PRECAUTIONS, Information for Patients, and Post-Marketing Experience Adverse Reactions sections.

The new WARNING is: Retinal Pigmentary Changes

Pigmentary changes in the retina, reported in the literature as pigmentary maculopathy, have been identified with long-term use of ELMIRON® (see ADVERSE REACTIONS). Although most of these cases occurred after 3 years of use or longer, cases have been seen with a shorter duration of use. While the etiology is unclear, cumulative dose appears to be a risk factor. Visual symptoms in the reported cases included difficulty reading, slow adjustment to low or reduced light environments, and blurred vision. The visual consequences of these pigmentary changes are not fully characterized. Caution should be used in patients with retinal pigment changes from other causes in which examination findings may confound the appropriate diagnosis, follow-up, and treatment. Detailed ophthalmologic history should be obtained in all patients prior to starting treatment with ELMIRON®. If there is a family history of hereditary pattern dystrophy, genetic testing should be considered. For patients with pre-existing ophthalmologic conditions, a comprehensive baseline retinal examination (including color fundoscopic photography, OCT, and auto-fluorescence imaging) is recommended prior to starting therapy. A baseline retinal examination (including OCT and auto-fluorescence imaging) is suggested for all patients within six months of initiating treatment and periodically while continuing treatment. If pigmentary changes in the retina develop, then risks and benefits of continuing treatment should be re-evaluated, since these changes may be irreversible. Follow-up retinal examinations should be continued given that retinal and vision changes may progress even after cessation of treatment.1

Prescriber Actions:

- Inform patients that changes in vision should be reported and evaluated.
- Use caution in patients with retinal pigment changes from other causes in which examination findings may confound the appropriate diagnosis, follow-up, and treatment.
- Detailed ophthalmologic history should be obtained in all patients prior to starting treatment with ELMIRON®.
- For patients with a family history of hereditary pattern dystrophy, genetic testing should be considered.
- For patients with pre-existing ophthalmologic conditions, a comprehensive baseline retinal examination (including color fundoscopic photography, OCT, and auto-fluorescence imaging) is recommended prior to starting therapy.
- Baseline retinal examinations (including OCT and auto-fluorescence imaging) are suggested for all patients within 6 months of starting ELMIRON® and periodically during therapy.
- If pigmentary changes in the retina develop, the risks and benefits of continuing treatment should be re-evaluated, since these changes may be irreversible.
- Follow-up retinal examinations should be continued given that retinal and vision changes may progress even after cessation of treatment.1,6

Reporting Adverse Events:

Healthcare providers should report new cases of the adverse events described in this letter to Janssen (1-800-526-7736) or to FDA's MedWatch Adverse Event Reporting program online (at www.fda.gov/MedWatch), by facsimile (1-800-FDA-0178), by telephone (1-800-FDA-1088), or by returning the postage-paid FDA form 3500 (available at www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf) by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787.

This letter is not intended as a complete description of the benefits and risks related to the use of ELMIRON® capsules. For more information, please call the Janssen Medical Information Center at 1-800-JANSSEN (1-800-526-7736).

Please click here to read the full Prescribing Information for ELMIRON®

Sincerely,

Paul Burton, MD Vice President, Cardiovascular and Metabolism Medical Affairs Janssen Pharmaceuticals, Inc.

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