Important Safety Information on ELMIRON (pentosan polysulfate sodium) and the Risk of Pigmentary Maculopathy

2020/12/15

Audience
Healthcare professionals including urologists, urogynecologists, ophthalmologists, optometrists, family physicians, and pharmacists.

Key messages

- **Cases of pigmentary maculopathy have been reported with long-term use of ELMIRON.**
- **ELMIRON is now contraindicated in patients with a personal history of any macular pathology.**
- **Healthcare professionals are advised to:**
  - **assess the benefits and risks with their patients before initiating treatment with ELMIRON and periodically thereafter.**
  - **obtain detailed ophthalmologic history in all patients before starting treatment with ELMIRON.**
  - **perform baseline and regular retinal examinations for early detection of macular pathology.**
  - **counsel patients to report changes in vision such as difficulty reading, slow adjustment to low or reduced light, blurred vision including blurry or wavy vision near or in the centre of the field of vision.**
- **The Canadian Product Monograph for ELMIRON has been updated to include the new contraindication and further strengthen the information about the risk of pigmentary maculopathy.**

What is the issue?
Cases of pigmentary maculopathy have been reported with long-term use of ELMIRON. These changes may be irreversible, and retinal and vision changes may progress even after cessation of therapy.

Products affected
ELMIRON® (pentosan polysulfate sodium), 100 mg capsules.

Background information
ELMIRON (pentosan polysulfate sodium) is a glycosaminoglycan substitute indicated for the initial and maintenance treatment of interstitial cystitis.

Cases of pigmentary maculopathy 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.

ELMIRON is now contraindicated in patients with a personal history of any macular pathology. The Canadian Product Monograph for ELMIRON has been updated to include the new contraindication and further strengthen the information about the risk of pigmentary maculopathy in the *Warnings and Precautions (including the new Serious Warnings and Precautions Box) and Consumer Information* sections.

Information for consumers
ELMIRON is used for the treatment of inflammation and irritation of the bladder wall (interstitial cystitis).

Cases of retinal changes (pigmentary maculopathy) have been reported with long-term use of ELMIRON. Although most of these changes occurred in patients using the medication for 3 years or longer, some cases have been seen with use over a shorter period of time. This eye disease changes the centre of the retina (called the 'macula'), which may harm the patient's vision and may lead to a permanent decrease or loss of central vision.

Before taking ELMIRON, patients should talk to their healthcare professional if they have a personal or family history of eye disease that affects the retina. Patients who have a personal history of eye disease that affects the retina should not use ELMIRON.

Before starting treatment with ELMIRON and during the treatment, patients should have regular eye exams that include checking the retina for detection of pigmentary maculopathy. Healthcare professionals will decide when these eye exams are needed, and if treatment with ELMIRON should be continued.

Patients should report to their healthcare professional any changes in their vision such as difficulty reading, slow adjustment to low or reduced light, blurred vision, blurry or wavy vision near or in the centre of their field of vision.

Patients should discuss any questions or concerns about this information with their healthcare professional.

Information for healthcare professionals
ELMIRON is now contraindicated in patients with a personal history of any macular pathology.

Healthcare professionals are advised to:

- assess the benefits and risks with their patients before initiating treatment with ELMIRON and periodically thereafter.

- obtain a detailed ophthalmologic history in all patients prior to starting treatment with ELMIRON.
- consider genetic testing for patients with a family history of hereditary macular pathology.
- recommend a comprehensive baseline retinal exam including colour fundoscopic photography, ocular coherence tomography , and auto-fluorescence imaging before initiating treatment in patients with pre-existing ophthalmologic conditions.
- recommend baseline and periodic comprehensive retinal examinations in patients continuing with ELMIRON treatment.
- counsel patients to report changes in vision such as difficulty reading, slow adjustment to low or reduced light, blurred vision including blurry or wavy vision near or in the centre of the field of vision.
- consider treatment discontinuation in the event pigmentary maculopathy is confirmed. Perform follow-up retinal examinations as retinal and vision changes may progress even after stopping treatment with ELMIRON.

Action taken by Health Canada
Health Canada, in collaboration with Janssen Inc., has updated the Canadian Product Monograph for ELMIRON to include the new contraindication and further strengthen the information about the risk of pigmentary maculopathy. Health Canada is communicating this important safety information to healthcare professionals and Canadians via the Recalls and Safety Alerts Database on the Healthy Canadians Web Site (https://healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php). This communication will be further distributed through the MedEffect™ e-Notice email notification system as well as through social media channels, including LinkedIn and Twitter.

Report health or safety concerns
Health Canada's ability to monitor the safety of marketed health products depends on healthcare professionals and consumers reporting adverse reactions and medical device incidents. Any case of pigmentary maculopathy or other serious or unexpected side effects in patients receiving ELMIRON should be reported to Janssen Inc. or Health Canada.

Janssen Inc.
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Toronto, ON, M3C 1L9
Tel: 1-800-567-3331
www.janssen.com/canada

To correct your mailing address or fax number, contact Janssen Inc.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:

Marketed Health Products Directorate
E-mail: mhpd_dpsc.public@hc-sc.gc.ca
Telephone: 613-954-6522
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