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EPAR summary for the public

Elmiron

pentosan polysulfate sodium

This is a summary of the European public assessment report (EPAR) for Elmiron. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Elmiron.

For practical information about using Elmiron, patients should read the package leaflet or contact their doctor or pharmacist.

What is Elmiron and what is it used for?

Elmiron is a medicine used to treat adults with bladder pain syndrome, a condition of the bladder which causes pain in the pelvic area and a frequent, urgent need to pass urine.

Elmiron is used in patients with moderate to severe pain and who have small bleeds or lesions (sores) in the bladder wall.

Elmiron contains the active substance pentosan polysulfate sodium.

How is Elmiron used?

Elmiron is available as 100-mg capsules and can only be obtained with a prescription. The recommended dose is one capsule taken three times a day.

Patients should be assessed every six months and treatment should be stopped if no improvement is seen.

For further information, see the package leaflet.

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How does Elmiron work?

The way the active substance in Elmiron, pentosan polysulfate sodium, works is not fully understood but it passes into the urine and is thought to attach to and help repair the protective layer of mucus lining the bladder, which is deficient in patients with bladder pain syndrome. This reinforcement of the protective layer may reduce inflammation and bladder pain.

What benefits of Elmiron have been shown in studies?

Because pentosan polysulfate sodium is a well-known substance, and its use in bladder pain syndrome is well established, the company for Elmiron presented data from the scientific literature. A review of 4 main studies from the literature showed that pentosan polysulfate sodium is effective at reducing symptoms, such as pain and the urge to pass urine frequently.

The studies involved a total of 454 patients with small bleeds and lesions in the bladder wall. Looking at the results of the 4 studies together, 1 in 3 (33%) patients taking pentosan polysulfate sodium showed an overall improvement in their condition compared with around 1 in 6 (16%) patients taking placebo (a dummy treatment).

What are the risks associated with Elmiron?

The most common side effects with Elmiron (which may affect up to 1 in 10 people) include headache, dizziness, and effects in the digestive systems such as diarrhoea, nausea (feeling sick), abdominal (belly) pain and bleeding from the rectum. Since Elmiron may have a weak anticoagulant effect (i.e. it may stop the blood from clotting properly), it must not be used in patients who actively bleed (but this does not include women during menstrual cycle). For the full list of all side effects and restrictions with Elmiron, see the package leaflet.

Why is Elmiron approved?

Bladder pain syndrome is a distressing condition for which no medicines were previously approved in the EU. In patients with small bleeds and lesions in the bladder wall, treatment with Elmiron led to significantly more patients having an overall improvement in symptoms.

No major safety concerns were identified, and the possible risk of bleeding can be minimised with appropriate precautions.

The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore decided that Elmiron's benefits are greater than its risks and recommended that it be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Elmiron?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Elmiron have been included in the summary of product characteristics and the package leaflet.

Other information about Elmiron

The European Commission granted a marketing authorisation valid throughout the European Union for Elmiron on 2 June 2017.

The full EPAR for Elmiron can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Elmiron, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2017.