23 March 2017
EMA/158291/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Elmiron

pentosan polysulfate sodium

On 23 March 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Elmiron, intended for the treatment of bladder pain syndrome characterised by either glomerulations or Hunner's lesions in the urine bladder mucosa. Elmiron was designated as an orphan medicinal product on 15 January 2015. The applicant for this medicinal product is bene-Arzneimittel GmbH.

Elmiron will be available as 100-mg hard capsules. The active substance of Elmiron is pentosan polysulfate sodium (ATC code: G04BX15). Pentosan polysulfate sodium is thought to have a local effect in the bladder after systemic administration and excretion into the urine by binding to and repairing the glycosaminoglycan layer in the deficient mucous of the bladder.

The benefits with Elmiron are its ability to relieve pain and urgency as well as to improve overall symptoms of the disease in adults with bladder pain syndrome. The most common side effects are headache, dizziness and gastro-intestinal events like diarrhoea, nausea, abdominal pain and rectal bleeding.

The full indication is: "treatment of bladder pain syndrome characterized by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition". It is proposed that Elmiron should be subject to medical prescription.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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