31 January 2019
EMA/CHMP/849632/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Febuxostat Krka

febuxostat

On 31 January 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Febuxostat Krka, intended for the prevention and treatment of hyperuricaemia. The applicant for this medicinal product is KRKA, d.d., Novo mesto.

Febuxostat Krka will be available as film-coated tablets (80 and 120 mg). The active substance of Febuxostat Krka is febuxostat, which decreases serum uric acid by selectively inhibiting xanthine oxidase (ATC code: M04AA03).

Febuxostat Krka is a generic of Adenuric, which has been authorised in the EU since 21 April 2008.Studies have demonstrated the satisfactory quality of Febuxostat Krka, and its bioequivalence to the reference product Adenuric. A question and answer document on generic medicines can be found here.

The full indication for the 80 mg tablets is:

Febuxostat Krka is indicated for the treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis).

Febuxostat Krka is indicated in adults.

The full indication for the 120 mg tablets is:

Febuxostat Krka is indicated for the treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis).

Febuxostat Krka is indicated for the prevention and treatment of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at intermediate to high risk of Tumor Lysis Syndrome (TLS).

Febuxostat Krka is indicated in adults.
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

[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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available in all official European Union languages after the marketing authorisation has been granted by the European Commission.