21 April 2017
EMA/221561/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Febuxostat Mylan

febuxostat

On 21 April 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 Febuxostat Mylan, intended for the prevention and treatment of hyperuricaemia. The applicant for this medicinal product is Mylan S.A.S.

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

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

The full indication is:

> "Febuxostat Mylan 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 Mylan 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 Mylan is indicated in adults."

The 80-mg tablets are only to be use for treatment of chronic hyperuricaemia, while the 120-mg tablets are for both treatment and prevention.

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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