



28 June 2018
EMA/CHMP/374196/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Duzallo

lesinurad / allopurinol

On 28 June 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Duzallo, intended for the treatment of hyperuricaemia in gout patients. The applicant for this medicinal product is Gruenthal GmbH.

Duzallo is a fixed dose combination of two active substances, lesinurad and allopurinol. It will be available as film-coated tablets (300 mg/200 mg and 200 mg/200 mg). Lesinurad is a selective uric acid reabsorption inhibitor that inhibits uric acid transporter 1, and allopurinol reduces uric acid production by inhibition of xanthine oxidase (ATC code: M04AA51).

The benefit of Duzallo is its ability to lower the level of uric acid in plasma and urine through increased uric acid excretion and decreased uric acid production. The most common side effects are influenza, gastro-oesophageal reflux disease, headache and increased blood creatinine.

The full indication is: "Duzallo is indicated in adults for the treatment of hyperuricaemia in gout patients who have not achieved target serum uric acid levels with an adequate dose of allopurinol alone."

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

