17 December 2015
EMA/CHMP/824058/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zurampic

lesinurad

On 17 December 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zurampic, as adjunctive treatment of hyperuricaemia in combination with a xanthine oxidase inhibitor in adults with gout. The applicant for this medicinal product is AstraZeneca AB.

Zurampic will be available as 200 mg film-coated tablets. The active substance of Zurampic is lesinurad (ATC code: M04AB05), a selective uric acid reabsorption inhibitor that inhibits uric acid transporter 1 (URAT1).

The benefit of Zurampic is its ability to increase uric acid excretion and thereby lower serum uric acid levels. The most common side effects are headache, influenza, increased blood creatinine and gastro-oesophageal reflux.

The full indication for Zurampic is:

"Zurampic, in combination with a xanthine oxidase inhibitor, is indicated in adults for the adjunctive treatment of hyperuricaemia in gout patients (with or without tophi) who have not achieved target serum uric acid levels with an adequate dose of a xanthine oxidase inhibitor 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

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