



The European Agency for the Evaluation of Medicinal Products

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PRESS RELEASE

Committee for Proprietary Medicinal Products Meeting of 13 to 15 November 2001

The CPMP adopted 5 opinions on initial marketing authorisation applications at this meeting:

- Positive opinions for the triple application **Xapit** (parecoxib sodium), **Dynastat** (parecoxib sodium) and **Rayzon** (parecoxib sodium) from Pharmacia Europe EEIG indicated for the short-term treatment postoperative pain. Review by the EMEA began on 31 October 2000 and the opinion was adopted on 15 November 2001, with an active review time of 204 days.
- A positive opinion for **Lumigan** (bimatoprost) from Allergan Pharmaceuticals (Ireland) Ltd. indicated for the treatment of elevated intraocular pressure in chronic open angle glaucoma and ocular hypertension. Review by the EMEA began on 26 December 2000 and the opinion was adopted on 15 November 2001, with an active review time of 178 days.
- A positive opinion for **Kineret** (anakinra) from Amgen Europe B.V. (The Netherlands) indicated for the treatment of the signs and symptoms of rheumatoid arthritis in combination with methotrexate, in patients with an inadequate response to methotrexate alone. Kineret treatment should be initiated and supervised by specialist physicians experienced in the treatment and diagnosis of rheumatoid arthritis. Review by the EMEA began on 18 July 2001 and the opinion was adopted on 15 November 2001, with an active review time of 204 days.

Summaries of opinions are available on the EMEA web site: <http://www.emea.eu.int>

The CPMP adopted an urgent safety restriction for Metalyse (tenecteplase) following a number of reports suggesting that the instructions for use may not have been followed properly. A public statement describing this was issued on 12 November 2001. The wording of the instructions for use in both the summary of product characteristics and the product labelling will be revised based on the CPMP recommendations. Metalyse is indicated for thrombolytic treatment of acute myocardial infarction. The marketing authorisation holder is Boehringer Ingelheim International GmbH. The authorisation was granted on 23 February 2001.

A more detailed CPMP meeting report will be made available next week, including details from the MRFG meeting of 12 November 2001.

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