European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 21 February 2008
Doc.Ref. EMEA/CHMP/80751/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
ADENURIC

International Nonproprietary Name (INN): ***febuxostat***

On 21 February 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Adenuric, 80 mg and 120 mg, film-coated tablets intended for treatment of chronic hyperuricaemia in gout patients. The applicant for this medicinal product is Ipsen Manufacturing Ireland Limited.

The active substance of Adenuric is febuxostat, a medicinal product against gout and inhibits uric acid production (ATC Code MO4AA03); febuxostat is a non-purine selective inhibitor of xanthine oxidase.

The benefits with Adenuric are its potency to reduce serum urate. The most common side effects are liver function abnormalities, diarrhoea, headache, nausea and rash. In the clinical trials serious cardiovascular adverse events were the main safety concern.

A pharmacovigilance plan for Adenuric, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history or presence of, tophus and/or gouty arthritis)".

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Adenuric and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu