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

London, 23 July 2009
Doc. Ref.: EMEA/CHMP/441193/2009

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

International Non-proprietary Name (INN): ***repaglinide***

On 23 July 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion**, recommending the granting of a marketing authorisation for the medicinal product Enyglid 0.5 mg, 1 mg, 2 mg tablets intended for the treatment of type 2 diabetes. The applicant for this medicinal product is Krka, d.d., Novo mesto.

The active substance of Enyglid is Repaglinide, a short-acting oral secretagogue that is a carbamoylmethyl benzoid acid derivative (ATC code: A10BX02). Repaglinide lowers the blood glucose levels acutely by stimulating the release of insulin from the pancreas, an effect dependent upon functioning β-cells in the pancreatic islets.

Enyglid is a generic of NovoNorm, which has been authorised in the EU since 17 August 1998. Studies have demonstrated the satisfactory quality of Enyglid, and its bioequivalence with NovoNorm. A question-and-answer document on generic medicines can be found here.

The approved indication is: "Repaglinide is indicated in patients with type 2 diabetes (Non Insulin-Dependent Diabetes Mellitus (NIDDM)) whose hyperglycaemia can no longer be controlled satisfactorily by diet, weight reduction and exercise. Repaglinide is also indicated in combination with metformin in type 2 diabetes patients who are not satisfactorily controlled on metformin alone. Treatment should be initiated as an adjunct to diet and exercise to lower the blood glucose in relation to meals."

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 the data submitted, considers that there is a favourable benefit risk balance for Enyglid, 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 7182
E-mail: mail@emea.europa.eu http://www.emea.europa.eu