



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2011
EMA/CHMP/450821/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion¹ (initial authorisation)

Trajenta linagliptin

On 23 June 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Trajenta, 5 mg, film-coated tablet intended for the treatment of type 2 diabetes mellitus to improve glycaemic control. The applicant for this medicinal product is Boehringer Ingelheim International GmbH. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Trajenta is linagliptin, a dipeptidyl peptidase 4 (DPP-4) inhibitor (ATC code: A10BH05).

The benefit with Trajenta is its ability to lower blood glucose (by means of lowering of the HbA1c). The most common side effect is an increased incidence of hypoglycaemia (this effect was most pronounced when linagliptin was added to a background treatment of metformin and sulfonylurea).

A pharmacovigilance plan for Trajenta will be implemented as part of the marketing authorisation.

The approved indication is:

“Trajenta is indicated in the treatment of type 2 diabetes mellitus to improve glycaemic control in adults:

as **monotherapy**

- in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contraindicated due to renal impairment.

as **combination therapy**

- in combination with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control.

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.



- in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.”

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 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 there to be a favourable benefit to risk balance for Trajenta and therefore recommends the granting of the marketing authorisation.