EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 May 2012
EMA/CHMP/321580/2012
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Jentadueto

linagliptin/metformin hydrochloride

On 24 May 2012 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Jentadueto, 2.5 mg/850 mg, 2.5 mg/1000 mg, film-coated tablets intended for the treatment of type 2 diabetes mellitus in adults.

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 substances of Jentadueto (ATC code: A10BD11, Drugs used in diabetes, combinations of oral blood glucose lowering drugs) are linagliptin and metformin hydrochloride. Linagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor. DPP-4 inhibition reduces the cleavage and inactivation of the active (intact) form of the incretin hormone glucagon-like peptide 1 (GLP-1) and glucose dependent insulinotropic polypeptide (GIP), producing an elevation of incretin concentrations that leads to enhancement of glucose dependent insulin secretion and a reduction in glucagon release. This way linagliptin improves glycaemic control by reducing fasting and postprandial glucose concentrations in patients with type 2 diabetes. Metformin is a biguanide and has an antihyperglycaemic effect, lowering both basal and postprandial plasma glucose concentrations. It is thought to act via various mechanisms, including decreasing hepatic glucose production, decreasing intestinal absorption of glucose, and improving insulin sensitivity by increasing peripheral glucose uptake and utilisation. Jentadueto combines these two glucose-lowering agents with complementary mechanisms of action.

The benefits with Jentadueto are its reduction of blood glucose levels (by means of lowering HbA1c) in patients inadequately controlled by metformin alone or by metformin and a sulphonylurea; and as being equivalent in its glucose-lowering effect compared to the combined use of linagliptin 5 mg once daily and metformin twice daily as an alternative option for patients being treated with these two medicines as separate tablets already. The most common side effect is an increased incidence of hypoglycaemia (when combined with a sulphonylurea).

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

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

The approved indication is: “Treatment of adult patients with type 2 diabetes mellitus:

Jentadueto is indicated as an adjunct to diet and exercise to improve glycaemic control in adult patients inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of linagliptin and metformin.

Jentadueto is indicated in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea.”

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 Jentadueto and therefore recommends the granting of the marketing authorisation.