



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/CHMP/20616/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Eperzan albiglutide

On 23 January 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Eperzan, 30 mg and 50 mg, powder and solvent for solution for injection in pre-filled pen intended for the treatment of type 2 diabetes mellitus. The applicant for this medicinal product is GlaxoSmithKline Trading Services Limited. 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 Eperzan is albiglutide (ATC Code A10BX13) a glucagon-like peptide 1 (GLP-1) receptor agonist generated by fusion of a GLP-1 analogue to albumin, resulting in a much prolonged half life. Like native GLP-1, albiglutide leads to an enhancement of glucose-dependent insulin secretion and a reduction of glucagon release.

The benefits with Eperzan are its clinically relevant effect on glycaemic control in patients with type 2 diabetes when used in combination with other glucose-lowering medicinal products including insulin or on its own when metformin cannot be used. Eperzan has a neutral effect on body weight. The most common side effects are nausea, diarrhoea and injection site reactions.

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

The approved indication is: "Eperzan is indicated for the treatment of type 2 diabetes mellitus in adults to improve glycaemic control as: - Monotherapy: When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to contraindications or intolerance. - Add-on combination therapy: In combination with other glucose-lowering medicinal products including basal insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see section 4.4 and 5.1 for available data on different combinations)".

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.



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 made 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 Eperzan and therefore recommends the granting of the marketing authorisation.

Medicinal product no longer authorised