26 March 2015
EMA/CHMP/190945/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Synjardy

empagliflozin / metformin

On 26 March 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Synjardy, intended for the treatment of type 2 diabetes mellitus. The applicant for this medicinal product is Boehringer Ingelheim GmbH.

Synjardy will be available as 5 mg/850 mg, 5 mg/1000 mg, 12.5 mg/850 mg and 12.5 mg/1000 mg film-coated tablets.

The active substances of Synjardy are empagliflozin and metformin, blood glucose-lowering agents (ATC code: A10BD20). Empagliflozin blocks a protein in the kidney, the sodium-glucose co-transporter-2 (SGLT2). This action reduces glucose re-absorption in the kidney, leading to glucose excretion in the urine and thereby lowering levels of glucose in the blood. Metformin works, among other ways, by suppressing glucose production by the liver.

The benefits with Synjardy are its ability to improve glycaemic control. Metformin is considered first-line treatment, especially in overweight/obese patients. Empagliflozin added to metformin has been shown to confer an additional clinically relevant improvement in glycaemic control, thus justifying the combination of these substances.

The most common side effects of metformin are gastrointestinal symptoms such as nausea, vomiting, diarrhoea, abdominal pain and loss of appetite, as well as taste disturbance. The most common side effects of empagliflozin are hypoglycaemia (when used with sulphonylurea or insulin), genital and urinary tract infections, pruritus and increased urination.

The full indication is:

“Treatment of adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve 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

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- in patients inadequately controlled on their maximally tolerated dose of metformin alone
- in patients inadequately controlled with metformin in combination with other glucose-lowering medicinal products, including insulin (see sections 4.5 and 5.1 for available data on different combinations)
- in patients already being treated with the combination of empagliflozin and metformin as separate tablets."

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.