24 September 2015
EMA/CHMP/523224/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ebymect

dapagliflozin / metformin

On 24 September 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 Ebymect, intended for the treatment of type 2 diabetes mellitus. The applicant for this medicinal product is AstraZeneca AB.

Ebymect will be available as 5 mg/1000 mg and 5 mg/850 mg film-coated tablets. The active substance of Ebymect is dapagliflozin / metformin, a combination of two oral blood glucose-lowering medicines (ATC code: A10BD15).

Dapagliflozin is a competitive, reversible, selective and orally active inhibitor of sodium-glucose co-transporter 2 (SGLT2). It improves fasting and post-prandial plasma glucose levels by reducing renal glucose reabsorption leading to urinary glucose excretion. Metformin is a biguanide that lowers both basal and postprandial plasma glucose by various mechanisms. It does not stimulate insulin secretion and, therefore, does not produce hypoglycaemia.

The benefits with Ebymect are its ability to improve glycaemic control through reduction of blood glucose levels in patients inadequately controlled by metformin alone. The most common side effects are hypoglycaemia (when used with a sulfonylurea or insulin), nausea, vomiting, diarrhoea, abdominal pain, loss of appetite, vulvovaginitis, balanitis and related genital infections, urinary tract infection, dysuria and polyuria.

The full indication is:

“Ebymect is indicated in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control

- in patients inadequately controlled on their maximally tolerated dose of metformin alone
- in combination with other glucose-lowering medicinal products, including insulin, in patients

[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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

inadequately controlled with metformin and these medicinal products (see sections 4.4, 4.5 and 5.1 for available data on different combinations)

- in patients already being treated with the combination of dapagliflozin 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.