26 May 2016
EMA/CHMP/271065/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Qtern

saxagliptin / dapagliflozin

On 26 May 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Qtern, intended for the treatment of type 2 diabetes mellitus. The applicant for this medicinal product is AstraZeneca AB.

Qtern is a fixed-dose combination of saxagliptin and dapagliflozin, two oral blood glucose lowering medicines (ATC code: A10BD21). It will be available as film-coated tablets (containing 5 mg saxagliptin and 10 mg dapagliflozin). Saxagliptin is a dipeptidyl peptidase 4 (DPP-4) inhibitor. DPP-4 inhibition reduces the cleavage and inactivation of the incretin hormone glucagon-like peptide 1 (GLP-1), leading to an increase in incretin levels, which in turn stimulates glucose-dependent insulin secretion and inhibits the release of glucagon. Dapagliflozin is a competitive, reversible, selective and orally active inhibitor of the human sodium-glucose co-transporter 2 (SGLT2) which reduces renal glucose re-absorption leading to urinary glucose excretion.

The benefit with Qtern is its ability to lower blood glucose. The most common side effect is upper respiratory tract infection. When used with a sulphonylurea hypoglycaemia may occur.

The full indication is:

“Qtern, fixed dose combination of saxagliptin and dapagliflozin, is indicated in adults aged 18 years and older with type 2 diabetes mellitus:

- to improve glycaemic control when metformin and/or sulphonylurea (SU) and one of the monocomponents of Qtern do not provide adequate glycaemic control,
- when already being treated with the free combination of dapagliflozin and saxagliptin.

(See sections 4.2, 4.4, 4.5 and 5.1 for available data on combinations studied.)”

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

[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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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.