19 September 2019
EMA/CHMP/478963/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Qtrilmet

metformin hydrochloride / saxagliptin / dapagliflozin

On 19 September 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Qtrilmet, intended for the treatment of type 2 diabetes mellitus. The applicant for this medicinal product is AstraZeneca AB.

Qtrilmet is a fixed-dose combination of metformin hydrochloride, saxagliptin and dapagliflozin, three oral blood glucose lowering medicines (ATC code: A10BD25). It will be available as modified-release tablets containing 850 mg metformin hydrochloride, 2.5 mg saxagliptin and 5 mg dapagliflozin, or 1000 mg metformin hydrochloride, 2.5 mg saxagliptin and 5 mg dapagliflozin.

Metformin is a biguanide with anti-hyperglycaemic effects, which lowers both basal and postprandial plasma glucose, saxagliptin is a dipeptidyl peptidase 4 (DPP-4) inhibitor, while dapagliflozin is a selective and reversible inhibitor of the human sodium-glucose co-transporter 2 (SGLT2).

The benefit with Qtrilmet is its ability to lower blood glucose. The most common side effects are upper respiratory tract infections and gastrointestinal symptoms. When used with an insulin or a sulphonylurea the risk of hypoglycaemia occurring can increase.

The full indication is:

"Qtrilmet is indicated in adults aged 18 years and older with type 2 diabetes mellitus:

- to improve glycaemic control when metformin with or without sulphonylurea (SU) and either saxagliptin or dapagliflozin does not provide adequate glycaemic control,
- when already being treated with metformin and saxagliptin and dapagliflozin."

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.

[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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