30 March 2023
EMA/CHMP/141137/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Qaialdo

spironolactone

On 30 March 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Qaialdo, intended for the treatment of refractory oedema associated with excessive aldosterone excretion. The applicant for this medicinal product is Nova Laboratories Ireland Limited.

Qaialdo will be available as a 10 mg/ml oral suspension. The active substance of Qaialdo is spironolactone, an aldosterone antagonist (ATC code: C03DA01). It competitively inhibits mineralocorticoid receptors in the kidneys to promote excretion of water and sodium and retention of potassium.

Qaialdo is a hybrid medicine[2] of Aldactone which has been authorised in the EU since 13-03-1975. Qaialdo contains the same active substance as Aldactone. Compared to the reference medicinal product, Qaialdo has a different pharmaceutical form (oral suspension) and strength.

Studies have demonstrated the satisfactory quality of Qaialdo, and its bioequivalence to the reference product Aldactone.

Because Qaialdo is bioequivalent to the reference medicine, its benefits and risks are taken as the same. The most common side effects are hyperkalaemia, particularly in patients with renal impairment or in those receiving ACE-inhibitors or angiotensin II antagonists concomitantly, gynaecomastia and breast pain.

The full indication is:

> In the management of refractory oedema associated with congestive cardiac failure; hepatic cirrhosis with ascites and oedema, malignant ascites, nephrotic syndrome, diagnosis and treatment of primary aldosteronism, essential hypertension.

[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
[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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Neonates, children and adolescents should only be treated under guidance of a paediatric specialist. There is limited paediatric data available (see sections 5.1 and 5.2).

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.