14 September 2023
EMA/CHMP/209632/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Aqumeldi

enalapril maleate

On 14 September 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a Paediatric Use Marketing Authorisation (PUMA) for the medicinal product Aqumeldi, intended for the treatment of heart failure in children from birth to less than 18 years.

The applicant for this medicinal product is Proveca Pharma Limited.

Aqumeldi will be available as a 0.25 mg orodispersible tablet. The active substance of Aqumeldi is enalapril maleate, an angiotensin converting enzyme inhibitor (ATC code: C09AA02). It acts on the renin-angiotensin system, blocking the formation of angiotensin II. This lowers blood pressure and increases the supply of blood and oxygen to the heart.

The benefits of Aqumeldi in children under 18 years of age are likely to be similar to those seen in adults with chronic heart failure, based on the pharmacokinetic response to the medicine. The most common side effects are cough, vomiting, microalbuminuria, hyperkalaemia, hypotension and postural dizziness.

Aqumeldi is a hybrid medicine[2] of Renitec which has been authorised in the EU since 06 September 1985. Aqumeldi contains the same active substance as Renitec, but is available at lower dosage strength and in a formulation more appropriate for children.

Studies have demonstrated the satisfactory quality of Aqumeldi.

The full indication is:

> AQUMELDI is indicated for the treatment of heart failure in children from birth to less than 18 years.

Aqumeldi should be initiated by physicians experienced in the treatment of paediatric patients with heart failure.

Detailed recommendations for the use of this product will be described in the summary of product

[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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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.