EMA/429786/2023
EMEA/H/C/005731

# Aqumeldi (*enalapril*)

An overview of Aqumeldi and why it is authorised in the EU

## What is Aqumeldi and what is it used for?

Aqumeldi is used in children and adolescents from birth to 17 years of age to treat heart failure (when the heart is not able to pump enough blood around the body).

Aqumeldi contains the active substance enalapril and is a 'hybrid medicine'. This means that it is similar to an authorised reference medicine containing the same active substance, but there are certain differences between the two. Aqumeldi is available at a lower dose than its reference medicine, Renitec, and in a different form that is appropriate for children.

## How is Aqumeldi used?

The medicine can only be obtained with a prescription and treatment should be started by a doctor experienced in the treatment of children with heart failure.

Aqumeldi is taken daily. It is available as tablets that dissolve in the mouth (orodispersible tablets).

For more information about using Aqumeldi, see the package leaflet or contact your doctor or pharmacist.

## How does Aqumeldi work?

Aqumeldi belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors. The medicine blocks ACE from forming the hormone angiotensin II, which is involved in raising blood pressure. By blocking the formation of angiotensin II, Aqumeldi helps to lower blood pressure and increases the supply of blood and oxygen to the heart.

## What benefits of Aqumeldi have been shown in studies?

The company provided the results from three studies looking at how Aqumeldi given at different doses behaves in the body. One study was carried out in healthy adults. Two studies were carried out in children from birth to 17 years of age with heart failure, caused either by dilated cardiomyopathy or congenital heart disease, two types of heart conditions.

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These studies showed that treatment with Aqumeldi in children leads to similar levels of enalapril to those achieved with authorised enalapril treatment in adults. Aqumeldi is therefore expected to be similarly effective at treating heart failure in children and adults.

The company also provided information from the published literature on the benefits and risks of enalapril when used off label in children with heart failure.

## What are the risks associated with Aqumeldi?

For the full list of side effects and restrictions with Aqumeldi, see the package leaflet.

The most common side effects with Aqumeldi (which may affect up to 1 in 10 people) include cough, vomiting, microalbuminuria (low levels of the protein albumin in urine), hyperkalaemia (high levels of potassium in the blood), hypotension (low blood pressure), and postural dizziness (dizziness when standing up).

Aqumeldi must not be used in people who are hypersensitive (allergic) to enalapril, to any other ACE inhibitors or to any of the other ingredients of Aqumeldi (which are listed in the package leaflet). It must also not be used in people who have had angioedema (rapid swelling under the skin) associated with previous ACE inhibitor therapy and in patients with hereditary or idiopathic (when the cause is unknown) angioedema. Aqumeldi must not be used during the second and third trimesters of pregnancy.

Patients with diabetes or kidney problems must not use Aqumeldi in combination with aliskiren-containing medicines (used to treat essential hypertension [high blood pressure of unknown cause]).

Aqumeldi must also not be used in combination with medicines containing sacubitril and valsartan (other medicines for heart failure) due to the increased risk of angioedema. Aqumeldi must not be given within 36 hours of switching to or from those medicines.

Finally, Aqumeldi must not be used in people with severe kidney problems.

## Why is Aqumeldi authorised in the EU?

Enalapril is authorised for treating heart failure in adults and is expected to work in the same way in adults and in children. Based on studies conducted in healthy adults and children with heart failure, as well as data from the published literature on the off-label use of enalapril in children with heart failure, Aqumeldi is expected to be effective at treating heart failure in children from birth to 17 years of age. In terms of safety, Aqumeldi was shown to be well tolerated, although data in babies below one month of age were limited.

The European Medicines Agency decided that Aqumeldi's benefits are greater than its risks and it can be authorised for use in the EU.

## What measures are being taken to ensure the safe and effective use of Aqumeldi?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Aqumeldi have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Aqumeldi are continuously monitored. Suspected side effects reported with Aqumeldi are carefully evaluated and any necessary action taken to protect patients.

## Other information about Aqumeldi

Aqumeldi received a marketing authorisation valid throughout the EU on 15 November 2023.

Further information on Aqumeldi can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/aqumeldi.

This overview was last updated in 11-2023.