EMA/162307/2023
EMEA/H/C/005535

Qaialdo (spironolactone)

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

What is Qaialdo and what is it used for?

Qaialdo is a medicine used to manage refractory oedema (swelling due to fluid build-up that does not respond to standard treatments) associated with any of the following conditions:

- congestive heart failure (when the heart does not pump blood as well as it should and fluid builds up around the heart and in the legs);
- hepatic cirrhosis (liver scarring) with ascites (fluid build-up in the belly) and oedema (fluid build-up in the legs, feet and ankles);
- malignant ascites (ascites caused by cancer cells spreading to the organs in the belly);
- nephrotic syndrome (a group of symptoms associated with kidney damage, such as the presence of protein in the urine or oedema);
- essential hypertension (high blood pressure without a known cause).

It can also be used to diagnose and treat primary aldosteronism, a condition in which the body produces too much of the hormone aldosterone, which also results in oedema.

Qaialdo is a 'hybrid medicine'. This means that the medicine is similar to a 'reference medicine' containing the same active substance, but Qaialdo is available as a liquid to be taken by mouth while the reference medicine is available as tablets. The reference medicine for Qaialdo is Aldactone.

Qaialdo contains the active substance spironolactone.

How is Qaialdo used?

The medicine can only be obtained with a prescription, and children should only be treated under supervision of a paediatric specialist.

Qaialdo is available as a suspension (a liquid with solid particles in it) to be taken by mouth once a day.

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

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How does Qaialdo work?

The active substance in Qaialdo, spironolactone, works by blocking the effects of aldosterone, a hormone that helps control water balance in the body. The medicine blocks specific receptors (targets) for aldosterone in the kidneys. This increases the elimination of salt and water in the form of urine while keeping levels of potassium from getting too low. This, in turn, reduces oedema.

What benefits of Qaialdo have been shown in studies?

Spironolactone has been used in the European Union for several decades to treat refractory oedema. As for every medicine, the company provided studies on the quality of Qaialdo. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

Because Qaialdo is bioequivalent to the reference medicine, its benefits are taken as being the same as the reference medicine's.

What are the risks associated with Qaialdo?

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

Because Qaialdo is bioequivalent to the reference medicine, its risks are taken as being the same as the reference medicine's.

The most common side effects with Qaialdo (which may affect more than 1 in 10 people) include hyperkalaemia (high blood potassium levels, which can cause tiredness, muscle weakness, feeling sick and heart rhythm disturbances). Gynaecomastia (breast growth in men) and breast pain are seen in up to 1 in 10 males.

Why is Qaialdo authorised in the EU?

Qaialdo has been shown to be comparable to the reference medicine. Therefore, the Agency's view was that, as for Aldactone, the benefits of Qaialdo outweigh the identified risks and it can be authorised for use in the EU.

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

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

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

Other information about Qaialdo

Qaialdo received a marketing authorisation valid throughout the EU on 26 May 2023.

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

This overview was last updated in 05-2023