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Amversio (*betaine anhydrous*)

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

What is Amversio and what is it used for?

Amversio is a medicine used to treat homocystinuria, an inherited disease where the amino acid homocysteine cannot be broken down and therefore builds up in the body. This causes a wide range of symptoms, including impaired vision, weak bones and circulatory problems.

It is used with other treatments, such as vitamin B6 (pyridoxine), vitamin B12 (cobalamin), folate and a special diet.

Amversio is a 'generic medicine'. This means that Amversio contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Cystadane. For more information on generic medicines, see the question-and-answer document here.

Amversio contains the active substance betaine anhydrous.

How is Amversio used?

Amversio can only be obtained with a prescription. Treatment with Amversio should be supervised by a doctor who has experience in the treatment of patients with homocystinuria.

Amversio is available as a powder to be taken by mouth. It should be dissolved fully in water, juice, milk, formula or food before being taken. The standard dose of Amversio is 50 mg per kilogram of body weight twice a day. The dose can be adjusted depending on the response to treatment (monitored by measuring the level of homocysteine in the blood). The aim of the treatment is to keep blood levels of homocysteine below 15 micromoles or as low as possible. This is usually achieved within a month.

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

How does Amversio work?

Betaine is a natural substance that is extracted from sugar beet. It reduces the high homocysteine levels in the blood of patients with homocystinuria by transforming homocysteine into the amino acid methionine. This helps to improve the symptoms of the disease.

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How has Amversio been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Cystadane, and do not need to be repeated for Amversio.

As for every medicine, the company provided studies on the quality of Amversio. There was no need for 'bioequivalence' studies to investigate whether Amversio is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Amversio is a water-soluble medicine with a composition very similar to the reference medicine's and both products are therefore expected to be absorbed in the same way in the gut.

What are the benefits and risks of Amversio?

Because Amversio is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Amversio authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Amversio has been shown to be comparable to Cystadane. Therefore, the Agency's view was that, as for Cystadane, the benefits of Amversio 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 Amversio?

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

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

Other information about Amversio

Further information on Amversio can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/amversio. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 03-2022.