EMA/410661/2020
EMEA/H/C/005359

Fampridine Accord (*fampridine*)

An overview of Fampridine Accord and why it is authorised in the EU

What is Fampridine Accord and what is it used for?

Fampridine Accord is a medicine used to improve walking ability in adults with multiple sclerosis (MS) who have a walking disability.

MS is a disease in which the immune system (the body's defences) attacks and damages the covering around the nerves and the nerves themselves in the brain and spinal cord.

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

Fampridine Accord contains the active substance fampridine.

How is Fampridine Accord used?

Fampridine Accord can only be obtained with a prescription and treatment should be supervised by a doctor experienced in treating MS. The medicine is available as tablets. The recommended dose is one tablet taken without food, twice a day, 12 hours apart.

After two or four weeks, patients are evaluated and those who have not shown an improvement should stop treatment. Patients continuing treatment beyond two or four weeks may have their treatment stopped if their walking ability worsens or if the patient does not report any benefit.

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

How does Fampridine Accord work?

For the body's muscles to contract, electrical impulses are transmitted along the nerves to the muscles. In MS, this transmission of electrical impulses is impaired when the covering around the nerves become damaged, which can lead to muscle weakness, muscle stiffness and difficulty walking.

The active substance in Fampridine Accord, fampridine, is a potassium channel blocker. It acts on damaged nerves, where it prevents charged potassium particles from leaving the nerve cells. This is

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believed to have the effect of allowing the electrical impulse to continue travelling along the nerves to stimulate the muscles, making it easier to walk.

How has Fampridine Accord 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, Fampyra, and do not need to be repeated for Fampridine Accord.

As for every medicine, the company provided studies on the quality of Fampridine Accord. 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.

What are the benefits and risks of Fampridine Accord?

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

Why is Fampridine Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Fampridine Accord has been shown to have comparable quality and to be bioequivalent to Fampyra. Therefore, the Agency's view was that, as for Fampyra, the benefits of Fampridine Accord 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 Fampridine Accord?

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

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

Other information about Fampridine Accord

Fampridine Accord received a marketing authorisation valid throughout the EU on 24 September 2020.

Further information on Fampridine Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/fampridine-accord. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 09-2020