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EPAR summary for the public

Fampyra

fampridine

This is a summary of the European public assessment report (EPAR) for Fampyra. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Fampyra.

For practical information about using Fampyra, patients should read the package leaflet or contact their doctor or pharmacist.

What is Fampyra and what is it used for?

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

MS is a disease of the nerves, in which inflammation destroys the protective sheath around the nerves.

It contains the active substance fampridine.

How is Fampyra used?

Fampyra is available as 10 mg tablets taken without food twice a day, 12 hours apart.

After two to four weeks, patients are evaluated and those who have not shown an improvement should stop treatment. Treatment should also be stopped if a patient's walking ability worsens or if the patient does not report any benefit.

The medicine can only be obtained with a prescription, and should be prescribed by a doctor experienced in treating MS. For further information, see the package leaflet.

How does Fampyra 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 protective sheaths around

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the nerves become damaged, which can lead to muscle weakness, muscle stiffness and difficulty walking.

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

What benefits of Fampyra have been shown in studies?

Two main studies in 540 patients with multiple sclerosis showed that Fampyra was more effective than placebo (a dummy treatment) at improving walking speed. The patients were treated for 9 or 14 weeks, with their waking speed measured along a 25 feet (7.5 metres) footpath.

In one of the studies 35% of patients taking Fampyra had higher walking speed on at least three out of four occasions than their quickest speed before treatment compared with 8% of patients taking placebo . In the second study the results were similar, with 43% of patients in the Fampyra group surpassing their previous best speed on three out of four occasions, compared with 9% in the placebo group.

A third study in 633 patients measured improvements in walking ability over 24 weeks using a rating scale known as the multiple sclerosis walking scale (MSWS), where patients rated how well they were able to do various activities such as walking, running or climbing stairs. In this study, 43% of patients taking Fampyra had at least an 8-point improvement in their MSWS score compared with 34% of those on placebo. (An 8-point improvement is considered clinically significant in this scale, which ranges from 0 to 100).

What are the risks associated with Fampyra?

The side effects seen with Fampyra are mostly neurological (relating to the brain or nerves) and include seizures (fits), insomnia (difficulty sleeping), anxiety, problems with balance, dizziness, paraesthesia (unusual sensations like pins and needles), tremor, headache and asthenia (weakness). The most common side effect reported in clinical studies, affecting around 12% of the patients, is urinary tract infection. For the full list of all side effects reported with Fampyra, see the package leaflet.

Fampyra must not be used with other medicines that contain fampridine or medicines known as ‘inhibitors of organic cation transporter 2’ such as cimetidine. It must not be used in patients who have seizures or have ever had seizures or in patients with kidney problems. For the full list of restrictions, see the package leaflet.

Why is Fampyra approved?

The studies with Fampyra showed that the medicine is likely to benefit approximately one third of patients with MS who have a walking disability, and that patients benefiting from the treatment can be identified at an early stage allowing treatment to be stopped in other patients. With regard to the medicine’s safety, serious side effects with Fampyra are rare.

The European Medicines Agency therefore concluded that the benefits of Fampyra outweigh its risks for patients with a walking disability and recommended that it be given marketing authorisation.

Fampyra was originally given 'conditional approval' because there was more evidence to come about the medicine. As the company has supplied the additional information necessary, the authorisation has been switched from conditional to full approval.

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

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

Other information about Fampyra

The European Commission granted a conditional marketing authorisation valid throughout the European Union for Fampyra on 20 July 2011. This was switched to a full marketing authorisation on 22 May 2017.

The full EPAR for Fampyra can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Fampyra, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2017