Fampridine PR (Fampyra)

This information sheet refers to a product that is not currently licensed in Ireland.

What is Fampridine PR?

Fampridine PR is a slow-release oral tablet being developed for people with all types of MS to improve walking ability. It is the first therapy approved to treat a specific symptom of MS and it can be used in combination with disease modifying therapies.

It is marketed by Biogen Idec under the trade name Fampyra in Europe or Ampyra in the US.

How does Fampridine PR work?

The tablet contains a sustained release formula of 4-Aminopyridine, which blocks tiny pores, or potassium channels, on the surface of nerve fibres. This blocking may improve the conduction of nerve signals in nerve fibres whose insulating myelin coating has been damaged by MS.

Taking Fampridine PR does not change the underlying course of the disease or limit the damage caused by the disease. It addresses the unmet medical need of walking improvement in MS with demonstrated efficacy in adults with MS.

How is Fampridine PR administered?

Fampridine PR is administered orally by tablet twice a day, 12 hours apart. It should be taken without food. Treatment with Fampyra is restricted to prescription and supervision by physicians experienced in the management of MS.

Who should take Fampridine PR?

In clinical trials, a proportion of people with all types of MS were found to benefit in terms of walking speed.

What does the research say?

There have been two phase three clinical trials completed to test efficacy:

Trial 1: 301 people with any type of MS were assigned to 14 weeks of treatment with either fampridine (10mg twice daily) or placebos. Sustained improvement in the time taken to walk 25 feet was used as the main indicator for walking improvement. The proportion of improvers was higher in the fampridine group (78/224 or 35%) than in the placebo group (6/72 or 8%). Improvement in walking speed was 25% in the fampridine group and 4.7% in the placebo group.

Trial 2: A second study was undertaken to confirm the results of the Trial 1, as well as establish how long the improvements lasted. Participants with any type of MS received treatment with either fampridine tablets twice daily (120 people) or placebo twice daily (119 people) for nine weeks. The time taken to walk 25 feet was again used as the primary measure during the course of the study. The results were similar with 43% of patients in the Fampridine PR group responding to treatment compared with 9% in the placebo group.

The results of these two studies indicate that: between one third to one half of people with walking difficulties will see an improvement in their walking speed after taking Fampridine PR. An average improvement of about 25% of walking speed would be expected from those that respond to the treatment.

Patients should be evaluated after two weeks and treatment should be stopped for those who have not shown an improvement. Treatment should also be stopped if a patient's walking ability worsens or if the patient does not report any benefit.

What are the side effects of taking Fampridine PR?

It was generally well tolerated in the clinical studies within the recommended dose of 10mg twice daily; most side effects were mild and resolved within hours or a few days.

The side effects seen were 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.

At higher doses, for example, 20 or 30mg twice daily, the risk of more serious side effects, including seizures, increases. For this reason it is important not to exceed the recommended daily dose.

Who should not take Fampridine PR?

Fampridine PR should not be taken by people who may be hypersensitive (allergic) to fampridine or any of the other ingredients. It should not be used

with other medicines that contain fampridine or medicines known as 'inhibitors of organic cation transporter 2' such as cimetidine. It should not be administered to patients who have seizures or have ever had seizures or in patients with kidney problems.

No data is available for Fampyra's safety or efficacy with respect to pregnant women, women breastfeeding and paediatric patients.

Why has Fampridine PR been approved for use?

The Committee on Medical Products for Human Use (CHMP), responsible for preparing the EMEA's opinions on all questions concerning medicines for human use, considered that Fampyra was 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.

The Committee noted that no other medicine was currently approved to treat the symptoms of MS and that the serious side effects with Fampyra were rare. The CHMP therefore concluded that the benefits of Fampyra outweigh its risks for patients with a walking disability and recommended that it be given 'conditional' marketing authorisation.

What information is still awaited for Fampridine PR?

In order to meet the obligations of conditional approval (which is renewable annually), a double-blinded, placebo-controlled, study on the long term efficacy and safety of Fampyra is being undertaken.

The study will look at the effects of Fampyra on other aspects of walking ability besides walking speed, investigating a broader primary endpoint clinically meaningful in terms of walking ability. It will further evaluate the early identification of responders in order to guide further treatment. A study report is to be submitted to the EMEA by June 2016. Every year, the European Medicines Agency will review any new information that may become available and update its position as necessary.

When will Fampridine PR be available in Ireland?

In Ireland, Fampyra underwent a rapid review by the National Centre for Pharamcoeconomics (NCPE), in September 2011, with the outcome that a full pharmaco-economic evaluation was recommended. This evaluation needs to be undertaken, and a positive recommendation is needed, in order for the drug to be considered for reimbursement in Ireland, for people with MS.

It is anticipated that the drug will be available for prescription in the Autumn of 2012.

What is MS Ireland's position on Fampyra?

MS Ireland considers Fampyra an important new treatment which addresses one of the most disabling symptoms of MS. We believe that once all the required paperwork has been through the NCPE and they approve the therapy it should immediately made available to people with MS.

We believe all people with MS should be given the opportunity to lead their best possible and most productive lives, using all licences and approved treatments available.

MS Ireland hopes that the drug will be made reimbursable under the HSE's drug reimbursement scheme so that all people with MS that could benefit from its administration would be able to access it irrespective of neither its cost nor their economic circumstance.

Disclaimer:
MS Ireland provides information to the MS Community on an array of topics associated with MS. This information is for reference purposes only and medical advice should always be sought before any treatment or intervention is tried.

Sources:

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