Fampridine (Fampyra)

Fact Sheet

Multiple Sclerosis Trust

MS

Information | Education | Research | Support

We hope you find the information in this factsheet helpful. If you would like to speak with someone about any aspect of MS, contact the MS Trust information team and they will help find answers to your questions.

This factsheet has been provided free by the Multiple Sclerosis Trust, a small UK charity which works to improve the lives of people affected by MS. We rely on donations, fundraising and gifts in wills to be able to fund our services and are extremely grateful for every donation received, no matter what size.

MS Trust information service

Helping you find the information you need

The MS Trust offers a wide range of publications, including a newsletter *Open Door*, which provides an ongoing update on research and developments in MS management. In addition it contains articles from people with MS and health professionals.

For a full list of MS Trust publications, to sign up for Open Door and much more visit our website at www.mstrust.org.uk

Freephone 0800 032 3839 (Lines are open Monday – Friday 9am-5pm)

email infoteam@mstrust.org.uk

write MS Trust
Spirella Building
Letchworth Garden City
SG6 4ET

Fampridine (Fampyra)

Date of issue: Oct 2011
Review date: Oct 2012

Contents

1. Introduction

Fampridine (brand name Fampyra) has been developed for the improvement of walking in people with multiple sclerosis (MS).

Following a positive recommendation from the Committee for Medicinal Products (CHMP) in May 2011[1], the European Commission has given conditional marketing authorisation for fampridine to improve walking in adult patients with MS who have walking disability (defined as scoring 4-7 on the Expanded Disability Status Scale). The Expanded Disability Status Scale (EDSS) is a widely used measure of neurological disability. Fampridine was launched in the UK in October 2011.

A conditional marketing authorisation is granted when a medicinal product is considered to fulfil an unmet medical need and should be made available despite the fact that further data are still required. In this case, the marketing authorisation is conditional on Biogen Idec conducting further research about the benefits and long-term safety of fampridine. In particular, the study will provide information on benefits beyond the effect on walking speed. A conditional approval is renewable annually.

Walking problems affect a large proportion of people with MS. One study suggested that 15 years after diagnosis, people with MS face a 40% probability of needing some form of walking assistance[2]. Difficulties with walking can be caused by balance or coordination problems, dizziness, numbness or other sensory changes in feet or legs, muscle stiffness (spasticity) or weakness. Because of the range of possible causes of walking difficulties, a multidisciplinary team of specialist health professionals may be involved in managing this aspect of MS. Input from a physiotherapist is particularly important.

2. What is fampridine?

Fampridine is a slow-release formulation of 4-aminopyridine, a potassium channel blocker. Fampridine is marketed in Europe by Biogen Idec.

In the USA, the drug is known as dalfampridine, brand name Ampyra.

3. How does fampridine work?

Cells of the nervous system, called nerve cells or neurons, are specialised to carry electrical signals by means of electrochemical messages. For muscles to contract, electrical signals must pass along the nerves to the muscles.

Myelin acts as insulation around the nerve cell, improving the transmission of these electric signals. When MS causes damage to the myelin, the transmission of the electrochemical messages along nerve cells is reduced. Fampridine works by interacting with the electrochemical process to allow the electrical signals to continue travelling along damaged nerves to stimulate muscles.

Walking problems experienced by people with MS can be caused by a variety of factors. Fampridine may be effective for those whose walking impairment has been caused by reduced nerve transmission. For this reason, not everyone taking fampridine will see improvements in walking. In clinical trials, approximately one third to one half of people taking fampridine found walking speed improved.

4. How is fampridine given?

Fampridine is taken orally as slow-release tablets. The recommended dose is one 10mg tablet, twice daily.

5. Starting and evaluating fampridine treatment

Treatment with fampridine should be started and supervised by a specialist doctor experienced in the management of MS.

Initial treatment will normally be limited to two weeks by which time any clinical benefits will have been identified. A walking test, for example the time taken to walk 25 feet, is recommended to monitor any improvement in walking. If no improvement is observed, or if the person taking fampridine reports no benefit, fampridine should be discontinued.

6. Clinical trials of fampridine

Evidence for the effectiveness of fampridine to improve walking has been drawn from two phase III studies.

301 people with any type of MS were assigned to 14 weeks of treatment with either fampridine (10mg twice daily) or placebo[3]. 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.

A further trial was designed to confirm the results of previous studies and establish how long the effect lasted[4]. 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. More people in the fampridine group showed a consistent improvement in walking speed (42.9%) compared with placebo (9.3%). For those responding to fampridine, walking speed increased on average by 24.7%. The mean improvement in walking 8-12 hours after the last dose was 25.7%, indicating continued effectiveness of the drug during the period between doses. Other self-assessed and clinician-assessed measures of walking difficulties also

showed a significant improvement in fampridine responders compared to non-responders and those taking placebo.

Overall, the results of these two key 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
- For those responding to fampridine, an average improvement of about 25% of walking speed can be expected.

6. Side effects and contraindications

Fampridine 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. Common side effects experienced included dizziness, nausea, some agitation or wakefulness, back pain and balance disorders. At higher doses, eg 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.

7. References

1. Committee for Medicinal Products for Human Use (CHMP). Positive opinion on the marketing authorisation for Fampyra (fampridine). Date: May 2011. [cited 2011: July 22] Available from URL: http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion_-_Initial_authorisation/human/002097/WC500106531.pdf
2. Myhr KM, Riise T, Vedeler C et al. Disability and prognosis in multiple sclerosis: demographic and clinical variables important for the ability to walk and awarding of disability pension. Multiple Sclerosis 2001;7:59-65.
3. Goodman AD, Brown TR, Krupp LB et al. Sustained-release oral fampridine in multiple sclerosis: a randomised, double-blind, controlled trial. Lancet 2009;373:732-8.
4. Goodman AD, Brown TR, Edwards KR et al. A phase 3 trial of extended release oral dalfampridine in multiple sclerosis. Annals of Neurology 2010;68:494-502.

Please contact the MS Trust Information Team if you would like any further information about reference sources used in the production of this publication.