Ampyra – MS-walking drug

National Multiple Sclerosis Society

News Detail

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UPDATE: Ampyra™, Symptomatic Medicine Approved by FDA to Improve Walking for People with All Types of MS, Now Available by Prescription

UPDATED March 15, 2010 with additional FAQs

Ampyra™ (dalfampridine, formerly known as fampridine SR, from Acorda Therapeutics), which was approved by the U.S. FDA in January for its ability to improve walking in people with any type of MS, is now available by prescription. This is the first therapy specifically approved to treat a symptom of MS, and it represents a big step forward for the many people who may benefit. A National MS Society Webcast on Ampyra is now available, and frequently asked questions are provided below, including cost information.

- **A National MS Society video webcast/podcast from MS Learn Online that discusses Ampyra is now available.**
- Acorda has established a phone line that individuals may call for information:
- 1-888-881-1918.
- The full label with prescribing and patient information guide is now available on the FDA's Website (.pdf)

FREQUENTLY ASKED QUESTIONS

Q. What is Ampyra? (pronounced amPEERah)
A. Ampyra, formerly known as fampridine SR, is a tablet containing a sustained-release formula of 4-aminopyridine, which blocks tiny pores, or potassium channels, on the surface of nerve fibers. This blocking ability may improve the conduction of nerve signals in nerve fibers whose insulating myelin coating has been damaged by MS. The first studies of this potassium-blocking approach in people with MS were supported by the National MS Society.

Q. How is a "symptomatic therapy" different from the approved disease-modifying therapies for MS?
A. A symptomatic therapy is usually a drug that addresses a particular aspect of a disease, but taking it does not change the underlying course of the disease or limit the damage caused by the disease. There are many medications taken by people with MS to manage specific symptoms, such as spasticity, fatigue or depression. While there are FDA-approved disease-modifying therapies that are partially effective against some forms of

the disease, as well as rehabilitation and symptomatic treatments for some symptoms, until now there was no pharmacologic treatment available for MS-related difficulty walking.

Q. How common are walking problems among people with MS?
A. A recent survey among more than 1,000 individuals with MS and many of their family members examined the impact of difficulty walking on quality of life among people with MS and their families. Some two-thirds of patients reported difficulty walking and of these, 70% reported that such difficulty was the most challenging part of their MS, and most reported that difficulty walking restricts their daily activities significantly, including their ability to travel. (Read more about survey results)

Q. How Effective is Ampyra?
A. Two phase III clinical trials of the drug were sponsored by Acorda Therapeutics. In the first, involving 301 people with any type of MS, walking speed increased by 25% compared with placebo. Results of this study have been published (February 28, 2009 issue of The Lancet (2009 373;732-738, summarized here. Results from a later, second phase III study involving 240 people with MS, announced in 2008, confirmed the benefits seen in the first, finding that a significantly greater proportion of people on the therapy had a consistent improvement in walking speed compared to those who took placebo. Among those taking Ampyra who improved in walking speed, there was a statistically significant improvement in leg strength.

Further study and clinical practice may help determine the extent to which the drug may impact other functions not measured in the clinical trials, and provide hints as to which individuals are most likely to respond.

Q. What are the potential side effects of Ampyra?
A. In the first phase III study, common adverse events (side effects) experienced more often by those on active treatment included back pain, dizziness, insomnia, fatigue, nausea and balance disorder. Two serious adverse events led participants to discontinue taking the drug (one case of anxiety and one seizure in a person who developed sepsis from a urinary tract infection). In the second phase III study, additional common adverse events in those on therapy included urinary tract infection, falls, and headache.

Q. How is Ampyra taken?
A. In clinical trials, participants on active therapy took one tablet of the drug by mouth two times per day. According to a company press release, Ampyra will be taken two times a day, approximately 12 hours apart.

Q. When and how will Ampyra become available for prescription?
A. The company announced on March 1, 2010 that Ampyra is now available for prescription. The drug is distributed by mail through a network of specialty pharmacies. Acorda has established a team to provide support services to facilitate access to the drug for patients and healthcare providers.

Q. Who might benefit from taking Ampyra?
A. There is no way of knowing in advance whether any particular individual who has MS might benefit from taking Ampyra. In clinical trials, a proportion of people with all types of MS were found to benefit in terms of walking speed. This proportion ranged from 35% to

43% of those who took the drug in the two phase III clinical trials.

Q. Can anyone with MS take Ampyra?
A. Ampyra was approved for persons with any type of multiple sclerosis. However, the FDA's approval of Ampyra comes with the warning that the drug should NOT be taken by individuals with a history of seizures, or by those with moderate to severe renal impairment (CrCl 51–80 mL/min).

Q. What is renal impairment, and why is it important that those taking Ampyra have adequate renal function?
A. "Renal" refers to the kidneys, which in essence clean the blood. If a person has adequate kidney function, then Ampyra will be cleared from the blood to a sufficient degree between doses so as to maintain a steady drug level in the blood. If a person has moderate to severe kidney impairment, then there is a danger that the concentration of the drug will increase in the blood beyond the amount considered safe. The result could be increased side effects including seizures, which in clinical trials occurred infrequently. For the same reasons, Ampyra should not be taken in combination with other forms of 4-aminopyridine (4-AP, fampridine), since the active ingredient is the same.

Q. Will taking Ampyra make it possible to stop using my walking aids?
A. There are many different types of walking aids and they address many different types of movement issues, so there is no single answer to this question. It is important that people who try the drug NOT make changes related to walking aids until they determine whether and how the drug affects them. One concern is that in the second clinical trial, a side effect experienced by some participants was increased falling. For that reason, it is important that people taking this medication continue to use caution and discuss any proposed changes in walking aids with their health care provider.

Q. How much will Ampyra cost?
A. According to a company press release on February 3, 2010, the wholesale price of Ampyra will be $1,056 per 30-day supply. The actual retail cost to an individual will depend on many factors, such as the cost negotiated by his or her insurer.

Q. How was the price of Ampyra determined?
A. The Society was not privy to how or why Acorda chose the price point it set for Ampyra. But in public statements they have made on the subject, they advised that Ampyra is a novel therapy that provides a unique benefit to people with MS which goes beyond symptomatic relief. Their pricing reflects both the benefit to patients and their investment in developing the drug, which extended over many years.

Q. Can a person take Ampyra along with other MS medications, such as one of the disease-modifying therapies or symptomatic treatments?
A. According to the prescribing label, yes. The label does not list any medications that might interfere with or interact with this drug. One aspect of the clinical trials of Ampyra was that individuals enrolled continued to take whatever disease-modifying therapies they were using.

Q. Does a person need to be able to walk in order to be prescribed Ampyra?
A. The people who were enrolled in the clinical trials were selected for their ability to walk so that they could be tested for improved walking ability. There is currently insufficient

experience using this drug outside of the context of clinical trials to predict at what level of disability or mobility problems the drug would not help. This is a question that individuals should discuss with their health care provider. Further study and clinical practice may help determine the extent to which the drug may impact other functions not measured in the clinical trials, and provide hints as to which individuals are most likely to respond.

Q. Would increasing the recommended daily dosage better help some people?
A. No, in clinical trials there was no benefit seen in doses higher than the recommended prescription dose. There is a possible danger of taking more than is prescribed because of increased chances of adverse events including seizures.

Q. Would a person take Ampyra on an "as needed" basis, or every day?
A. This drug was designed to be taken two times per day at about 12 hours apart so that the amount of drug in the bloodstream is fairly steady. For that reason taking it on an "as needed" basis would probably not be helpful.

Q. How long would a person take Ampyra?
A. The clinical trials were of relatively short duration. Although there is insufficient information on the long-term use of Ampyra to know how long it may be taken, to date no new concerns have emerged in the safety extension studies. The duration of time that someone is on the drug will be determined by each person in consultation with his/her physician, likely based on whether it continues to provide benefit and does not cause unacceptable side effects.

Q. What will happen if an individual stops taking Ampyra – would walking issues get worse?
A. Based on experience from the clinical trials leading to the approval of Ampyra, it appears that walking ability in most individuals returns rapidly to the pre-treatment baseline after an individual stops taking the drug.

Q. Does Ampyra cause MS relapses?
A. Some people in the clinical trials of Ampyra experienced a worsening of their MS symptoms when they stopped taking the medication. It was unclear whether this reflected a return to their pre-trial state or an actual relapse, but the FDA did not make a distinction between the two when listing possible side effects. The FDA did, however, determine that the risk-benefit ratio for Ampyra is satisfactory.

Q. Are there any generic equivalents to Ampyra available?
A. No. Ampyra is a proprietary, sustained release formula and although it is similar to the basic chemical called 4-aminopyridine or fampridine, they are not interchangeable. For many years some compounding pharmacies have been making 4-aminopyridine for individual use. The problem with compounding, and one of the reasons many doctors were reluctant to prescribe the compounded version of 4-aminopyridine to people with MS, is that the compounded product increased the risk of inconsistent dosing and the potential for seizures. Having access to a thoroughly tested, sustained release formula in the FDA-approved version called Ampyra is important to people with MS because, as the FDA pointed out during its advisory panel review of clinical trials, there is a narrow therapeutic window between drug efficacy and drug excess, which could result in possible seizures.

Q. How is Ampyra different from the 4-aminopyridine (4-AP) that has been obtainable for years from compounding pharmacies?
A. Though similar, Ampyra and 4-AP are not interchangeable as Ampyra is a proprietary formula, sustained-release version of 4-AP. 4-AP is a compound, which means that a compounding pharmacy orders the ingredients and mixes them to create a product for the customer. Over the years, many people have taken 4-AP this way—many with success, but quite a few with significant problems having to do with the fact that 4-AP lowers a person's seizure threshold (which means that taking any product made from 4-AP puts a person at greater risk for having a seizure). The problems arose for several reasons: First, the ingredients, which are ordered by compounding pharmacies from different places, seem to vary in purity and quality. Second, compounding pharmacies vary in quality as well and operate independently without the same regulatory oversight that exists for pharmaceutical products. The result has been significant variability in the quantity and quality of the compound being taken by people. Because, as the FDA pointed out during its panel review, there is a narrow therapeutic window between drug efficacy and drug excess, this variability has resulted in a significantly increased risk of having seizures.

The developers of Ampyra worked in a variety of ways to address these problems. They create a time-release formulation (fampridine) of the product to ensure that a person maintains an even level in the blood at all times, which reduces the risk of abruptly lowering the person's seizure threshold. Then they conducted clinical trials to determine the most effective dose with the lowest possible seizure risk. Ampyra is the result of those controlled trials. The FDA determined that the safety issues had been sufficiently addressed to approve it for MS patients.

Individuals who have been taking 4-AP through a compounding pharmacy are encouraged to discuss this issue with their doctors.

Q. Will Ampyra be covered by my health insurance plan?
A. Coverage for Ampyra will depend on individual insurance plans. Acorda has established a team to provide support services to help patients and healthcare professionals access the drug, including working with insurance carriers and providing patient assistance programs. According to the company, assistance available includes a program to limit co-payments and financial assistance for eligible individuals.

Q. Where can I get additional information about the support that Acorda will provide to help people gain access to Ampyra?
A. Acorda has established a phone line that individuals may call for information: 1-888-881-1918. The company has established a team to provide support services to help patients and healthcare professionals access the drug, including working with insurance carriers and providing patient assistance programs such as co-pay mitigation.

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