Fampiron-ER

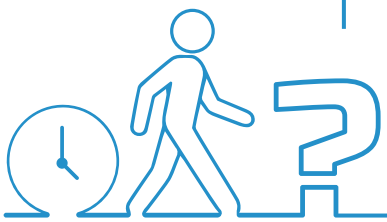
Fampridine Extended Releas 10mg

Mobility Matters in MS

Fampiron is used in adult patients living with multiple sclerosis to improve walking speed. it belongs to a group of medicines called potassium channel blockers. They work by stopping potassium leaving the nerve cells which have been damaged by multiple sclerosis. This medicine is thought to work by letting signals pass down the nerve more normally, allowing people to walk better.

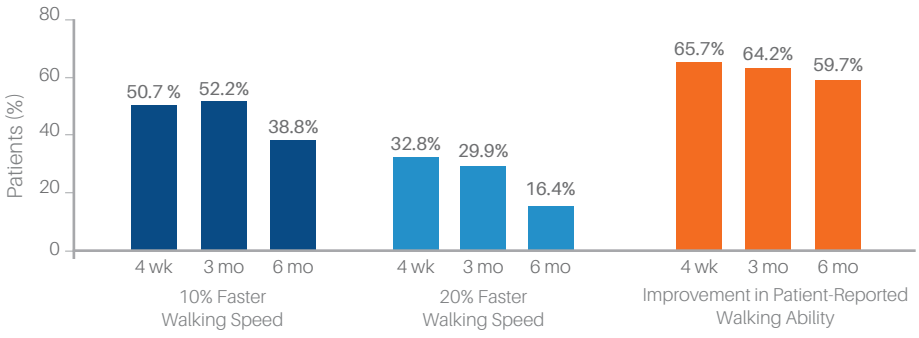
Improvement in Walking-Related Activities:

- Standing
- Maintaining Balance
- Ability to Walk
- Walking Distances
- Climbing Stairs
- Walking Speed



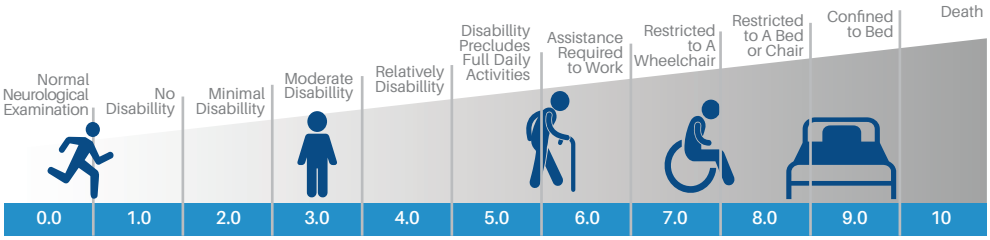
According to a study of the effect of fampridine on gait parameters of 120 adults with MS, Eighty-three patients (74%) were found to be responders. response to treatment was defined as a 15% improvement in at least one of the following tests: the Timed 25-Foot-Walk (T25FW), the 2-min walk test (2MWT) and the Multiple Sclerosis Walking Scale (MSWS-12)[1].

Short-Term Treatment, Long Term Relief[3-5]:



Patients were treated with PR-fampridine 10mg twice daily over 6 months. Walking speed was assessed using the T25FW; patient-reported walking ability was assessed using the MSWS-12. Any improvement in MSWS-12 score was considered improvement in patient-reported walking ability. For the T25FW, thresholds of ≥10% and ≥20% improvement in walking speed were used. The total number of patients who were treated with PR-fampridine (N=67) was used to calculate the proportions of patients who demonstrated improvement in walking speed or patient-reported walking at each visit to provide an overall description of the rate of clinical response based on the initial cohort of patients treated[2].

The EDSS:



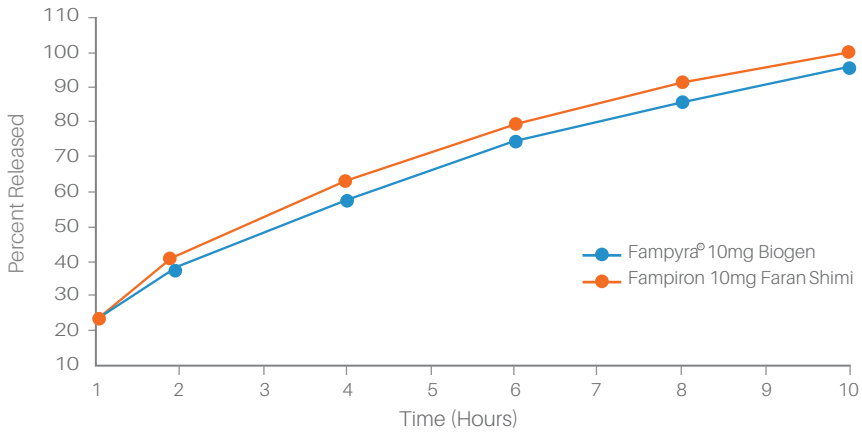
The Future of Fampridine:

Fampridine has other potential uses that remain to be discovered, but they seem promising:

- Quality of Life[1]
- Fatigue[1]
- Optic Neuritis[5]
- Nystagmus[6]
- Episodic Ataxia[7]

Bioequivalence Study of Fampiron_ER:

Fampiron-ER 10mg (manufactured by Faran Shimi pharmaceutical Company) and Fampyra-ER 10mg (manufactured by Biogen UK) according to FDA guidance for industry entitled "Bioavailability and Bioequivalence studies submitted in NDAs or INDs_General considerations" were bioequivalent. Also, it is worth to remark that this study was approved by the Iran Food and Drug Administration.



Comparative Dissolution Profile Fampridine from Test
(Fampiron 10mg Tablets, Faranshimi) and Refrence (Fampyra® ER 10mg Tablets, Biogen)

Dosing and Administration[3,4]:

- The recommended dose is one 10mg tablet, twice daily.

Maximum daily dose: 20mg.

*The tablets should be taken without food.

- **Missed Dose:** The usual dosing regimen should always be followed.

A double dose should not be taken if a dose is missed.

Use in specific populations:

- **Mild Renal Impairment:** (CrCl 51-80 ml/min) no dose adjustment needed; however, use with extreme caution as risk of seizure may be increased secondary to reduced clearance.
- **Moderate-to-severe renal impairment:** (CrCl≤ 50 ml/min) Use is contraindicated.
- **Hepatic Impairment:** No dose adjustment is required; the drug undergoes minimal metabolism and is primarily excreted unchanged in the urine.
- **Pediatric Population:** The safety and efficacy of Fampridine in children aged under 18 have not been established. No data are available.

Pregnancy & Breast-Feeding:

Information related to the use of fampridine in pregnancy is limited.

It is not known if fampridine is present in breast milk.

Contraindications:

Hypersensitivity to fampridine, 4-aminopyridine, or any component of the formulation; history of seizure; moderate or severe renal impairment (CrCl ≤50 mL/minute).

Precautions:

- Anaphylaxis
- Seizures
- Urinary Tract Infection

Interactions:

- **Cimetidine, Metformin, Quinidine:** Risk C: Monitor therapy.
- **Dolutegravir, Trilaciclib:** Risk D: Consider therapy modification.

Side effects:

Adverse reactions identified include urinary tract infection, seizure, insomnia, anxiety, balance disorder, dizziness, paraesthesia, tremor, headache and asthenia.

Rx Code: 69423

Reference:

1. Allart E, Benoit A, Blanchard-Dauphin A, Tiffreau V, Thevenon A, Zephir H, Outteryck O, Lacour A, Vermersch P. Sustained-released fampridine in multiple sclerosis: effects on gait parameters, arm function, fatigue, and quality of life. Journal of neurology. 2015 Aug;262(8):1936-45. 2. Prugger M, Berger T. Assessing the long-term clinical benefit of prolonged-release fampridine tablets in a real-world setting: a review of 67 cases. Patient related outcome measures. 2013;4:75.
3. https://www.uptodate.com/contents/dalfampridine-fampridine-drug-information. 4. https://www.medicines.org.uk/emc/product/4763/smpc#gref.
5. Horton L, Conger A, Conger D, Remington G, Frohman T, Frohman E, Greenberg B. Effect of 4-aminopyridine on vision in multiple sclerosis patients with optic neuropathy. Neurology. 2013 May 14;80(20):1862-6. 6. Glasauer S, Kalla R, Büttner U, Strupp M, Brandt T. 4-aminopyridine restores visual ocular motor function in upbeat nystagmus. Journal of Neurology, Neurosurgery & Psychiatry. 2005 Mar 1;76(3):451-3. 7. Strupp M, Kalla R, Claassen J, Adrion C, Mansmann U, Klopstock T, Freilinger T, Neugebauer H, Spiegel R, Dichgans M, Lehmann-Horn F. A randomized trial of 4-aminopyridine in EA2 and related familial episodic ataxias. Neurology. 2011 Jul 19;77(3):269-75.