

**PART III: CONSUMER INFORMATION**

**FAMPYRA™**

**Fampridine sustained release tablets**

**This leaflet is part III of a three-part "Product Monograph" published when FAMPYRA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about FAMPYRA. Contact your doctor or pharmacist if you have any questions about the drug.**

Make sure you read and understand the section, **PROPER USE OF THIS MEDICATION**. Follow the instructions. Ask your doctor or pharmacist to explain the proper use of FAMPYRA if you do not understand these instructions.

- **Take only one 10 mg tablet of FAMPYRA in the morning and one 10 mg tablet in the evening, 12 hours apart.**
- **Take the tablet whole and do not divide, crush, dissolve, suck or chew the tablet.**
- **You must always leave 12 hours between each tablet. Do not take two tablets at once to make up for a missed dose. Take your next tablet when you would normally take it.**
- **Taking more than one tablet at a time or more often than every 12 hours can increase the risk of having a serious side effect, such as a seizure.**
- **If you have taken more FAMPYRA than the prescribed dose, get emergency medical help immediately by contacting your regional Poison Control center or by calling 911. Tell them you are at risk of having a seizure after taking too much FAMPYRA.**

**ABOUT THIS MEDICATION**

**What the medication is:**

FAMPYRA may help adults (18 years and over) with multiple sclerosis (MS) related walking disability to walk better.

FAMPYRA can be used alone or with other medicines used to treat MS.

Multiple sclerosis is an autoimmune disease that affects the central nervous system (CNS). The CNS is made up of the brain, nerves and spinal cord. The nerves carry electrical and chemical messages from our brain to the rest of our body – giving us the ability to think, speak and move. When nerves are damaged by MS, the normal ability for these messages to move along the nerves may be lost. This leads to the neurological symptoms such as walking difficulties, numbness, vision problems, and imbalance.

**What it does:**

FAMPYRA contains the active substance fampridine, which belongs to a group of medicines called potassium channel blockers. The way that FAMPYRA works in MS patients is not fully understood. FAMPYRA is thought to work by blocking potassium channels, which may help messages to pass down the damaged nerve.

**When it should not be used:**

Do not take FAMPYRA if you:

- Have an allergy or are sensitive to fampridine or any ingredients in this medicine (listed below).
- Are taking 4-aminopyridine (4-AP) compounded by your pharmacist.
- Have ever had a seizure (also referred to as a fit or convulsion).
- Have kidney problems.

- Are taking any other medicine containing fampridine. This may increase your risk of serious side effects.
- Are taking medicines that will reduce the elimination of FAMPYRA from your body, which may increase your risk of serious side effects. Some of these medicines include cimetidine, and quinidine.
- Are taking other medicines that are known to increase the risk of seizures, such as bupropion, tramadol, tapentadol, or preparations used for colon cleansing.

FAMPYRA should not be used in children and adolescents under 18 years, because it has not been studied in MS patients younger than 18 years of age.

**What the medicinal ingredient is:**

The active ingredient in FAMPYRA is called fampridine.

**What the nonmedicinal ingredients are:**

The non-medicinal ingredients of FAMPYRA tablets are: hydroxypropyl methylcellulose USP, microcrystalline cellulose USP, colloidal silicon dioxide NF, magnesium stearate USP, hydroxypropyl methylcellulose/hypromellose USP, titanium dioxide USP, and macrogol/PEG 400 NF.

**What dosage forms it comes in:**

FAMPYRA comes as a 10 mg sustained release tablet.

**WARNINGS AND PRECAUTIONS**

BEFORE you use FAMPYRA talk to your doctor or pharmacist if:

- You have ever had a seizure. FAMPYRA should not be used by patients who have had seizures. FAMPYRA can increase the risk of seizures.

Ask your doctor if you have any factors or if you are taking any medicines that affect your risk of seizures.

- You have kidney disease. FAMPYRA should not be used by patients who have kidney problems.
- You have heart rhythm or conduction problems.
- You have a history of nerve pain in the face (trigeminal neuralgia).
- You are pregnant or planning to become pregnant.
- You are breastfeeding or plan to breastfeed.

Tell your doctor if you have any other medical conditions.

Before starting treatment and regularly during treatment, your doctor should check that your kidneys are working properly.

Serious allergic reactions have been observed in patients treated with Fampyra. Signs of allergic reaction may include rash, itching, difficulty breathing, swelling of the face, lips, tongue or throat. In several cases, these reactions occurred after the first dose. Seek immediate emergency assistance if you develop any of these signs or symptoms.

This medicine may make you feel dizzy or unsteady and this may increase the risk of falling. If you use a walking aid, such as a cane, you should continue to use it as needed.

**Risk of Seizure**

It is important that you take only one 10 mg tablet of FAMPYRA in the morning and one 10 mg tablet in the evening, 12 hours apart. Do not divide, crush, dissolve, suck or chew the tablet. Taking more than one tablet at a time or more often than every 12 hours, or taking a broken tablet can increase the risk of having a serious side effect, such as a seizure.

- If you have taken more FAMPYRA than the prescribed dose, get emergency medical help immediately by contacting your regional Poison Control center or by calling 911. Tell them you are at risk of having a seizure after taking too much FAMPYRA.

- If you think you missed a dose, do not take two tablets at once to make up for a missed dose. Take your next tablet when you would normally take it. You must always leave 12 hours between each tablet.

### INTERACTIONS WITH THIS MEDICATION

Tell your doctor about all of the medicines you take now or have taken recently, including prescription and non-prescription medicines. This includes any vitamin or mineral supplement, or herbal products.

Do not start any new medicines until you talk to your doctor who prescribed FAMPYRA.

- 4-aminopyridine and other medicines containing fampridine: Do not take FAMPYRA if you are taking 4-aminopyridine (4-AP, fampridine) compounded by your pharmacist. These medicines contain the same active ingredient as FAMPYRA and should be discontinued before starting FAMPYRA, to reduce the risk of serious side effects.
- Medicines that affect the kidneys: Your doctor will be especially careful if FAMPYRA is given at the same time as any medicine that may affect your kidney function. Tell your doctor if you are taking medicines such as beta blockers (carvedilol, pindolol, propranolol), procainamide, metformin, ranitidine, and varenicline.

Some medicines that affect kidney function should not be taken with FAMPYRA. Examples of these medicines include cimetidine and quinidine.

### PROPER USE OF THIS MEDICATION

Always follow your doctor's instructions for taking FAMPYRA. You should check with your doctor or pharmacist if you are not sure. **Do not take more than the prescribed dose.**

#### Dose:

Take one 10 mg tablet of FAMPYRA in the morning and one tablet in the evening. **You must leave 12 hours between each tablet. Do not take a tablet**

**more often than every 12 hours.** The tablets are to be taken without food.

Swallow each tablet whole, with a drink of water. If you cannot swallow FAMPYRA tablets whole, tell your doctor.

Do not divide, crush, dissolve, suck or chew the tablet. A broken tablet can release too much of the drug at one time. This can increase your risk of having a seizure.

Your doctor should assess your walking ability before you start FAMPYRA and again within the first 4 weeks of treatment. If you and your doctor decide there has not been benefit to you in this period, treatment should be stopped.

If the decision is to continue treatment, it is important that you and your doctor continue to periodically reassess whether you are experiencing benefit, and to stop taking the drug if you are not.

#### Overdose:

Take only the dose your doctor has prescribed you. Do not change your dose of FAMPYRA. If you take more than your prescribed dose, there is a risk of seizure.

If you have taken more FAMPYRA than your doctor has prescribed, seek emergency help immediately by contacting your regional Poison Control Centre or by calling 911, even if there are no symptoms. Tell them you are at risk of having a seizure after taking too much FAMPYRA. Take the medication package with you if you go to the hospital.

#### Missed Dose:

If you forget to take a tablet, **do not take two tablets at once to make up for a missed dose.** You must always leave 12 hours between each tablet.

**Taking more than your prescribed dose can increase the risk of serious side effects.**

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, FAMPYRA can have side effects. If you have any worrying side effects including any that are not included here, contact your doctor or pharmacist.

**Seizures:** Some patients have had seizures while taking FAMPYRA, including patients who have never had seizures before. If you have a seizure while taking FAMPYRA get emergency help right away and do not take any more FAMPYRA.

Serious allergic reactions have been observed in patients treated with Fampyra Signs of allergic reaction may include rash, itching, difficulty breathing, swelling of the face, lips, tongue or throat. In several cases, these reactions occurred after the first dose. Seek immediate emergency assistance if you develop any of these signs or symptoms.

**FAMPYRA can cause side effects. Please review the information in the table carefully.**

**Very common side effects** (affect more than 1 in 10 patients).

Urinary tract infection

**Common side effects** (affect between 1 and 10 in every 100 patients).

Feeling unsteady, dizziness, headache, feeling weak and tired, difficulty sleeping, anxiety, tremor (minor shaking), numbness or tingling of the skin, sore throat, shortness of breath, feeling sick (nausea), being sick (vomiting), constipation, upset stomach, back pain.

**Uncommon side effects** (affect between 1 and 10 in every 1000 patients).

Worsening of nerve pain in the face (trigeminal neuralgia).

If any of these side effects affects you severely, tell your doctor right away.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek emergency medical assistance
		Only if severe	In all cases	
<b>Common</b> (affects more than 1 in 10 patients).	Shortness of breath			√
<b>Un-common</b> (affects between 1 and 10 in every 1,000 patients)	Seizure (i.e. loss of consciousness with uncontrollable shaking)			√
	Allergic reaction (symptoms include rash, itching, difficulty breathing, swelling of the face, lips, tongue or throat)			√

*This is not a complete list of side effects. For any unexpected effects while taking FAMPYRA, contact your doctor or pharmacist.*

**HOW TO STORE IT**

Store FAMPYRA at room temperature (between 15 to 30° C). Store the tablets in the original bottle to protect them from light and moisture. Each bottle contains 14 tablets and a silica gel desiccant. Do not take your medicine after the expiry date shown on the bottle or carton.

Keep out of reach and sight of children.

Medicines should not be disposed of in waste water or household garbage. Ask your pharmacist how to dispose of medicines you no longer need.

**REPORTING SUSPECTED SIDE EFFECTS**

**You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:**

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- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:  
- **Fax toll-free to 1-866-678-6789, or**

- **Mail to: Canada Vigilance Program**

**Health Canada**

**Postal Locator 0701D**

**Ottawa, Ontario**

**K1A 0K9**

**Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).**

***NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.***

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This document plus the full Product Monograph, prepared for health professionals can be obtained by contacting Biogen Idec Canada Inc. at:

1-855-676-6300.

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**MORE INFORMATION**

FAMPYRA™ is marketed under license from Acorda Therapeutics, Inc. and is manufactured for Acorda under license from Alkermes Pharma Ireland Limited (APIL), utilizing APIL's MatriX Drug Absorption System (MXDAS™) technology. MXDAS™ is a trademark of Alkermes Pharma