

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrFAMPYRA™

Fampridine extended-release tablets

Read this carefully before you start taking **FAMPYRA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **FAMPYRA**.

What is FAMPYRA used for?

FAMPYRA is used to improve walking in adults with Multiple Sclerosis (MS) related walking disability.

How does FAMPYRA work?

In MS, inflammation destroys the protective layer around the nerves. This leads to muscle weakness, muscle stiffness and difficulty walking.

FAMPYRA contains the active substance fampridine, which belongs to a group of medicines called potassium channel blockers. It works by stopping potassium leaving the nerve cells which have been damaged by MS. FAMPYRA is thought to work by letting signals pass down the nerve more normally, which allows you to walk better.

What are the ingredients in FAMPYRA?

Medicinal ingredients: fampridine

Non-medicinal ingredients: colloidal silicon dioxide, hypromellose, macrogol/PEG 400, magnesium stearate, microcrystalline cellulose, and titanium dioxide.

FAMPYRA comes in the following dosage forms:

Extended-Release tablets: 10 mg

Do not use FAMPYRA if:

- you are allergic to fampridine or any of the other ingredients in FAMPYRA or its packaging.
- you are taking 4-aminopyridine (4-AP) compounded by your pharmacist.
- you are taking any other medicine containing fampridine. This may increase your risk of serious side effects.

- your healthcare professional has told you that you have moderate or severe kidney problems
- you have a seizure or ever had a seizure (also referred to as a fit or convulsion).
- you 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.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take FAMPYRA. Talk about any health conditions or problems you may have, including if you:

- have any factors or are taking any medicines which affect your risk of seizures.
- have heart rhythm or conduction problems.
- are prone to infections.
- use a walking aid, such as a cane. FAMPYRA may make you feel dizzy or unsteady and may increase your risk of falling. If you use a walking aid, you should continue to use it as needed.
- have a history of nerve pain in the face (trigeminal neuralgia). FAMPYRA may make your condition worse.
- are taking medicines that may affect your kidney function, such as:
 - beta blockers, which are medicines used to treat high blood pressure such as carvedilol, pindolol, or propranolol.
 - procainamide, a medicine used to treat abnormal heart rhythms.
 - metformin, a medicine used to treat type 2 diabetes.
 - ranitidine, a medicine used to treat ulcers of the stomach or intestines.
 - varenicline, a medicine used to help you stop smoking.

Other warnings you should know about:

FAMPYRA can cause serious side effects, including:

- **Seizures (fits):** Your risk of seizures increases when you take FAMPYRA, especially if you:
 - take more than the prescribed dose of FAMPYRA.
 - do not take FAMPYRA as prescribed.
 - take certain medicines at the same time (e.g. bupropion, tramadol, tapentadol, or preparations used for colon cleansing).
 - have kidney problems or other factors that increases your risk of seizures as determined by a healthcare professional.
- **Allergic reactions:** Serious allergic reactions have been observed in patients treated with FAMPYRA. Symptoms included rash, itching, difficulty breathing, swelling of the face, lips, tongue or throat. In several cases, these reactions occurred after the first

dose. If you experience an allergic reaction, **stop** taking FAMPYRA and tell your healthcare professional **right away**.

See the **Serious side effects and what to do about them** table, below, for more information on these and other serious side effects.

Urinary tract infection (UTI): An increase in UTIs has been noted in patients taking FAMPYRA. If you experience signs of a UTI, such as difficult or painful urination, bladder pain, or abdominal pain, tell your healthcare professional **right away**.

Infection: FAMPYRA may reduce the number of cells that fight infection in the body (white blood cells). This can make you more likely to get an infection. Tell your healthcare professional **right away** if you notice signs of an infection, such as fever or chills, severe diarrhea, shortness of breath, prolonged dizziness, headache, stiff neck, weight loss, or apathy.

Driving and using machines: FAMPYRA may cause dizziness, balance problems, or fatigue. You should not drive or use tools or machinery until you know how you respond to FAMPYRA.

Pregnancy: FAMPYRA is not recommended during pregnancy. If you become pregnant or think you are pregnant while taking FAMPYRA, contact your healthcare professional **right away**. Your healthcare professional will consider the benefit of you being treated with FAMPYRA against the risk to your baby.

Breast-feeding: It is not known if FAMPYRA can pass into breast milk and harm your baby. Therefore, FAMPYRA should not be used during breast-feeding. Talk to your healthcare professional about ways to feed your baby while taking FAMPYRA.

Check-ups and testing:

- Your healthcare professional will evaluate your risk of seizures before you are prescribed FAMPYRA. They will tell you if it is right for you.
- Your healthcare professional will assess your walking ability before you start FAMPYRA and within the first 4 weeks of treatment. If you and your healthcare professional decide there has not been any improvements during this period, the treatment will be stopped. If the decision is to continue treatment, you and your healthcare professional will continue to regularly monitor your walking ability. Your treatment will be stopped if you are not experiencing any benefit.
- Your healthcare professional may also do blood tests before you start FAMPYRA and regularly during treatment. This is to check if your kidneys are working properly.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with FAMPYRA:

- other medicines containing fampridine.
- 4-aminopyridine (4-AP), a medicine compounded by a pharmacist that manages some of the symptoms of MS, and improves the ability to walk in adults.

- medicines that will reduce the elimination of FAMPYRA from your body, such as cimetidine, and quinidine.
- medicines that may affect your kidney function, such as:
 - beta blockers, which are medicines used to treat high blood pressure such as carvedilol, pindolol, or propranolol.
 - procainamide, a medicine used to treat abnormal heart rhythms.
 - metformin, a medicine used to treat type 2 diabetes.
 - ranitidine, a medicine used to treat ulcers of the stomach or intestines.
 - varenicline, a medicine used to help you stop smoking.
- medicines that may affect your risk of seizures, such as bupropion, tramadol, tapentadol, or preparations used for colon cleansing.

Ask your healthcare professional if you are not sure whether the medicines you take are in the list above.

How to take FAMPYRA:

- Take FAMPYRA exactly as your healthcare professional tells you. Do not take more than the prescribed dose.
- Take FAMPYRA without food.
- Swallow tablet whole, with a drink of water. If you cannot swallow FAMPYRA tablets whole, tell your healthcare professional.
- Do not divide, crush, dissolve, suck or chew the tablet. A broken tablet can release too much of the medicine at one time. This can increase your risk of having a seizure.

Usual dose:

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

Overdose:

Symptoms of an overdose include:

- confusion
- excessive sweating
- seizures
- memory loss (amnesia)
- involuntary movements, shaking or twitching
- abnormal heart rhythms
- high blood pressure

If you think you, or a person you are caring for, have taken too much FAMPYRA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget or miss a dose of FAMPYRA, skip the missed dose and take the next dose as scheduled. **Do not double the dose to make up for the missed dose.** You must always leave 12 hours between each tablet. Taking more than your prescribed dose can increase your risk of experiencing serious side effects.

What are possible side effects from using FAMPYRA?

These are not all the possible side effects you may feel when taking FAMPYRA. If you experience any side effects not listed here, tell your healthcare professional.

Very common side effects:

- Urinary tract infection

Common side effects:

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

Uncommon side effects:

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

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Dyspnea (shortness of breath)			√
RARE			
Seizures (fits): loss of consciousness with uncontrollable shaking			√
Allergic reaction: difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat.			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store FAMPYRA at room temperature (between 15 to 30 °C).
- Store the tablets in the original bottle to protect from light and moisture.
- Discard your medicine after the expiry date shown on the packaging.
- Keep out of reach and sight of children.

If you want more information about FAMPYRA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the Biogen Canada Inc.'s website (<https://www.biogen.ca>), or by calling 1-855-676-6300.

This leaflet was prepared by Biogen Canada Inc.

Last Revised JAN 24, 2022

FAMPYRA™ is marketed under license from Acorda Therapeutics, Inc. and is manufactured for Acorda under license from Alkermes Pharma Ireland Limited (APIL). FAMPYRA™ is a trademark of Acorda Therapeutics, Inc.

© Biogen [2012]. All rights reserved.