

FAMPYRA®

(fam-peer-a)

Fampridine (fam-pri-deen)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FAMPYRA. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the benefits FAMPYRA is expected to have for you, against the risks of taking it.

If you have any questions about taking this medicine, ask your doctor or pharmacist or contact the Multiple Sclerosis (MS) Society in your state or region.

Keep this leaflet with the medicine.

You may need to read it again.

What FAMPYRA is used for

FAMPYRA is used in adult patients with Multiple Sclerosis (MS) to improve walking. 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 MS.

This medicine is thought to work by letting signals pass down the nerve more normally, which allows you to walk better.

Your doctor, may prescribe FAMPYRA for another purpose. Ask your doctor if you have any questions about why FAMPYRA has been prescribed for you.

There is no information on the use of this medicine in those below 18 years of age.

This medicine is available only with a doctor's prescription.

Before you take FAMPYRA

When you must not take it

Do not take FAMPYRA if:

- 1. you have an allergy to FAMPYRA or any of the ingredients listed at the end of this leaflet**

Some of the symptoms of an allergic reaction may include, shortness of breath, wheezing or difficulty breathing,

swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.

2. you are currently taking other forms of fampridine (4-amino pyridine).

Taking FAMPYRA with other forms of fampridine may increase the risk of seizures, fits or convulsions.

Ask your doctor or pharmacist if you are not sure if you have been taking one of these medicines.

3. you have ever had a seizure or you have been told by your doctor you have a high risk of seizure (also referred to as a fit or convulsion)

FAMPYRA may increase the risk of seizures, fits or convulsions.

Some patients may be at a higher risk of seizure than others, due to other ongoing medical conditions. Your doctor will discuss your full medical history to advise on your seizure risk.

4. you have serious problems with your kidneys

In patients with serious kidney disease FAMPYRA may increase the risk of side effects.

Your doctor will be especially careful if fampridine is given at the same time as any medicine which may affect how your kidneys eliminate medicines for example carvedilol, propranolol and metformin.

Do not take FAMPYRA if the packaging is torn or shows signs of tampering.

Do not take FAMPYRA if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should start taking FAMPYRA, contact your doctor.

Before you start to take it

Tell your doctor if:

- 1. you are allergic to any other medicines, foods, dyes or preservatives**
- 2. you have or have had any other health problems or medical conditions, including:**
 - Problems with your kidneys
 - History of a seizure (also referred to as a fit or convulsion)
 - Sudden, repeated attacks of facial nerve pain known as trigeminal neuralgia
- 3. you are pregnant or intend to become pregnant.**

Your doctor will discuss the benefits and risks of using FAMPYRA when pregnant.

4. you are breastfeeding or wish to breastfeed.

Your doctor will discuss the benefits and risks of using FAMPYRA when breastfeeding.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking FAMPYRA.

How to take FAMPYRA

Take FAMPYRA exactly as your doctor has prescribed.

How much to take

The dose is one tablet taken in the morning and one tablet taken in the evening (12 hours apart). It is important to take the tablets 12 hours apart.

You must always leave 12 hours between tablets.

Follow all directions given to you by your doctor, pharmacist or MS education nurse carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How to take it

Swallow each tablet whole, with a drink of water.

Do not divide, crush, dissolve, suck or chew the tablet, as this may increase your risk of side-effects.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

Your doctor will assess whether FAMPYRA is working for you with a walk test after an initial 8 weeks of treatment. If a response isn't seen, your doctor will stop treatment.

If you forget to take it

Do not double a dose to make up for the dose you have missed.

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.

If you have any further questions on the use of this product, ask your doctor, pharmacist or MS education nurse.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Australian Poisons Information Centre (telephone 13 11 26) for advice, or the New Zealand National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken too much FAMPYRA, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much FAMPYRA, you may:

- Become confused
- Feel agitated with trembling or shaking
- Notice increased sweating
- Have a seizure, fit or convulsion
- Temporarily lose your memory

If you are not sure what to do, contact your doctor, pharmacist or MS education nurse.

While you are taking FAMPYRA

Things you must do

If you are about to be started on any new medicines, remind your doctor or pharmacist that you are taking FAMPYRA.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during the surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all your doctor's appointments so your progress can be checked.

Your doctor may do some tests from time to time to prevent unwanted side effects.

Things you must not do

Do not take FAMPYRA to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not take more than the recommended dose.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side-effects.

Things to be careful of

Be careful driving or operating machinery until you know how FAMPYRA affects you.

This medicine may cause dizziness or a feeling of unsteadiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FAMPYRA.

FAMPYRA helps most people with MS, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor, MS nurse or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- Urinary tract infection
- Headache
- Feeling weak
- Difficulty sleeping
- Sore throat
- Feeling sick (nausea)
- Being sick (vomiting)
- Constipation
- Upset stomach
- Back pain
- Dizziness
- Feeling unsteady
- Anxiety

- Numbness or tingling of the skin
- Tremor (minor shaking)
- Worsening of facial nerve pain in people with trigeminal neuralgia
- Spinning sensation (vertigo)

These are the more common side effects of FAMPYRA.

Tell your doctor immediately if you notice any of the following:

- seizure (also known as a fit or convulsion)

This is a serious side effect. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking FAMPYRA and tell your doctor immediately or go to casualty at your nearest hospital:

- Difficulty breathing (shortness of breath)
- Swelling of the face, mouth, lips, throat or tongue
- Reddening or itching of the skin

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

After taking FAMPYRA

Storage

Keep your tablets in their container until it is time to take them.

If you take the tablets out of their container they may not keep well.

Keep FAMPYRA in a cool, dry place where it stays below 25°C. Do not store it, or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking FAMPYRA, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What it looks like

Each FAMPYRA tablet is an off-white oval tablet with A10 on one side.

Ingredients

Each tablet of FAMPYRA contains 10 mg of fampridine. It also contains hypromellose, microcrystalline cellulose, silicon dioxide, magnesium stearate and the film coat (Opadry White Y-1-7000 E171) contains hypromellose, titanium dioxide and macrogol 400.

FAMPYRA does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Australian Register Number:

AUST R 170002

Supplier

FAMPYRA is supplied in Australia by:

Biogen Australia Pty Ltd

ABN 30 095 760 115

Level 4, 2 Banfield Road

Macquarie Park NSW 2113

Australia

FAMPYRA is supplied in New Zealand by:

Biogen NZ Biopharma Limited

Auckland, New Zealand

This leaflet was prepared in February 2021.

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

FAMPYRA[®] is a registered trademark of Acorda Therapeutics, Inc.