

FAMPYRA®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using FAMPYRA?

FAMPYRA contains the active ingredient fampridine. FAMPYRA is used in adult patients with Multiple Sclerosis (MS) to improve walking.

For more information, see Section [1. Why am I using FAMPYRA?](#) in the full CMI.

2. What should I know before I use FAMPYRA?

Do not use if you have ever had an allergic reaction to FAMPYRA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use FAMPYRA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FAMPYRA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use FAMPYRA?

- 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.
- 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.

More instructions can be found in Section [4. How do I use FAMPYRA?](#) in the full CMI.

5. What should I know while using FAMPYRA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using FAMPYRA.
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	<ul style="list-style-type: none"> • Keep all your doctor's appointments so your progress can be checked.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly. • Do not take more than the recommended dose.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how FAMPYRA affects you.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none"> • 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. • Use within 7 days after first opening a bottle. • Keep FAMPYRA in a cool, dry place where it stays below 25°C.

For more information, see Section [5. What should I know while using FAMPYRA?](#) in the full CMI.

6. Are there any side effects?

Common side effects may include: digestion system symptoms such as vomiting and nausea, constipation or upset stomach, unsteadiness, anxiety, numbness of the skin, tremor, facial nerve pain, urinary tract infection, headache, weakness, difficulty sleeping, sore throat or back pain.

Side effects that require seeking urgent medical help include: seizures and allergic reaction.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

FAMPYRA (fam-peer-a)

Active ingredient: *fampridine* (fam-pri-deen) 10 mg modified release (MR) tablet

Consumer Medicine Information (CMI)

This leaflet provides important information about using FAMPYRA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FAMPYRA.**

Where to find information in this leaflet:

- [1. Why am I using FAMPYRA?](#)
- [2. What should I know before I use FAMPYRA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use FAMPYRA?](#)
- [5. What should I know while using FAMPYRA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using FAMPYRA?

FAMPYRA contains the active ingredient fampridine. FAMPYRA 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.

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

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.

2. What should I know before I use FAMPYRA?

Warnings

Do not use FAMPYRA if:

- you are allergic to fampridine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
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.
- **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.

- **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.

- **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.

Check with your doctor if:

- you are allergic to any other medicines, foods, dyes, or preservatives take any medicines for any other condition
- 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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking other medicines?

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FAMPYRA.

4. How do I use FAMPYRA?

How much to take

- The dose is one tablet taken 12 hours apart.
- 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.

- Follow the instructions provided and use FAMPYRA until your doctor tells you to stop.

When to take FAMPYRA

- The dose is one tablet taken in the morning and one tablet taken in the evening (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.

How to take FAMPYRA

- Take FAMPYRA exactly as your doctor has prescribed.
- 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.

If you forget to use FAMPYRA

FAMPYRA should be used regularly at the same time each day. If you miss your dose at the usual time, do not take a double dose to make up for the dose you missed.

You must always leave 12 hours between each tablet.

If you use too much FAMPYRA

If you think that you have used too much FAMPYRA, you may need urgent medical attention.

You should immediately:

- phone the Australian Poisons Information Centre (**by calling 13 11 26**) or the New Zealand National Poisons Information Centre, (**by calling 0800 POISON or 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you take too much FAMPYRA, you may:

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

5. What should I know while using FAMPYRA?

Things you should do

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.

Call your doctor straight away if you:

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

Remind any doctor, dentist or pharmacist you visit that you are using FAMPYRA.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- 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.

- Use within 7 days after first opening a bottle.
- Keep FAMPYRA in a cool, dry place where it stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it 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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

FAMPYRA helps most people with MS, but it may have unwanted side effects in some people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Digestion system-related: <ul style="list-style-type: none">• Feeling sick (nausea)• Being sick (vomiting)	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> • Constipation • Upset stomach <p>Nervous system-related:</p> <ul style="list-style-type: none"> • Dizziness • Feeling unsteady • Anxiety • Numbness or tingling of the skin • Tremor (minor shaking) • Nerve pain in the face occurring for the first time • Worsening of facial nerve pain in people with trigeminal neuralgia • Spinning sensation (vertigo) <p>Urinary tract-related:</p> <ul style="list-style-type: none"> • Urinary tract infection <p>Nonspecific side effects:</p> <ul style="list-style-type: none"> • Headache • Feeling weak • Difficulty sleeping • Sore throat • Back pain 	

Serious side effects

Serious side effects	What to do
<p>Nervous system-related:</p> <ul style="list-style-type: none">• Seizure (also known as a fit or convulsion) <p>This is a serious side effect. You may need urgent medical attention.</p> <p>Allergic reaction-related:</p> <ul style="list-style-type: none">• Difficulty breathing (shortness of breath)• Swelling of the face, mouth, lips, throat, or tongue• Reddening or itching of the skin <p>These are very serious side effects. You may need urgent medical attention or hospitalisation.</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>Serious side effects are rare.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What FAMPYRA contains

Active ingredient (main ingredient)	fampridine
Other ingredients (inactive ingredients)	hypromellose microcrystalline cellulose silicon dioxide magnesium stearate

	the film coat (Opadry White Y-1-7000 E171) contains: titanium dioxide macrogol 400
Potential allergens	None

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

Do not take this medicine if you are allergic to any of these ingredients.

What FAMPYRA looks like

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

FAMPYRA - AUST R 170002.

Further information

You can obtain more information from your doctor, pharmacist or nurse or by telephoning 1800 852 289 in Australia or 0800 852 289 in New Zealand.

Who distributes FAMPYRA

FAMPYRA is supplied in Australia by:

Biogen Australia Pty Ltd

Level 4, 2 Banfield Road

Macquarie Park NSW 2113

Australia

FAMPYRA is supplied in New Zealand by:

Biogen NZ Biopharma Limited

Auckland, New Zealand

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