1. What Fampyra is and what it is used for

Fampyra is a medicine used to improve walking in adults (18 years and over) with Multiple Sclerosis (MS) related walking disability. In multiple sclerosis, inflammation destroys the protective sheath around the nerves leading 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. 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.

2. What you need to know before you take Fampyra

Do not take Fampyra

- if you are allergic to fampridine or any of the other ingredients of this medicine (listed in section 6)
- if you have a seizure or have ever had a seizure (also referred to as a fit or convulsion)
- if you have kidney problems
- if you are taking a medicine called cimetidine
- if you are taking any other medicine containing fampridine. This may increase your risk of serious side effects

Tell your doctor and do not take Fampyra if any of these apply to you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fampyra:

- if you feel aware of your heartbeat (palpitations)
- if you are prone to infections
- you should use a walking aid, such as a cane, as needed
− because this medicine may make you feel dizzy or unsteady this may result in an increased risk of falls
− if you have any factors or are taking any medicine which affects your risk of fits (seizure).

Tell your doctor before you take Fampyra if any of these apply to you.

Children and in adolescents

Do not give Fampyra to children or adolescents under the age of 18 years.

Older people

Before starting treatment and during treatment your doctor may check that your kidneys are working properly.

Other medicines and Fampyra

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Fampyra if you are taking any other medicine containing fampridine.

Other medicines that affect the kidneys

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, propanolol and metformin.

Fampyra with food and drink

Fampyra should be taken without food, on an empty stomach.

Pregnancy and breast-feeding

If you are pregnant, or are planning to become pregnant, tell your doctor before you take Fampyra.

Fampyra is not recommended during pregnancy.

Your doctor will consider the benefit of you being treated with Fampyra against the risk to your baby.

You should not breast-feed whilst taking this medicine.

Driving and using machines

Fampyra may have an effect on people’s ability to drive or use machines, it can cause dizziness. Make sure you’re not affected before you start driving or use machinery.

3. How to take Fampyra

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Fampyra is only available by prescription and under the supervision of doctors experienced in MS.

Your doctor will give you an initial prescription for 2 to 4 weeks. After 2 to 4 weeks the treatment will be reassessed.

The recommended dose is
One tablet in the morning and one tablet in the evening (12 hours apart). Do not take more than two tablets in a day. **You must leave 12 hours** between each tablet. Do not take the tablets more often than every 12 hours.

Swallow each tablet whole, with a drink of water. Do not divide, crush, dissolve, suck or chew the tablet. This may increase your risk of side effects.

If your Fampyra is supplied in bottles, the bottle will also contain a desiccant. Leave the desiccant in the bottle, do not swallow it.

**If you take more Fampyra than you should**

**Contact your doctor immediately** if you take too many tablets.
Take the Fampyra box with you if you go to see the doctor.
In overdose you may notice sweating, minor shaking (tremor), confusion, memory loss (amnesia) and fits (seizure). You may also notice other effects not listed here.

If you forget to take Fampyra

**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 medicine, ask your doctor or pharmacist.

4. **Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you have a seizure, stop taking Fampyra** and tell your doctor immediately.

If you experience one or more of the following allergic (hypersensitivity) symptoms: swollen face, mouth, lips, throat or tongue, reddening or itching of the skin, chest tightness and breathing problems **stop taking Fampyra** and see your doctor immediately.

Side effects are listed below by frequency:

**Very Common side effects**

May affect more than 1 in 10 people:
• Urinary tract infection
Common side effects

May affect up to 1 in 10 people:

- Feeling unsteady
- Dizziness
- Headache
- Feeling weak and tired
- Difficulty sleeping
- Anxiety
- Minor shaking (tremor)
- Numbness or tingling of skin
- Sore throat
- Common cold (nasopharyngitis)
- Flu (influenza)
- Difficulty breathing (shortness of breath)
- Feeling sick (nausea)
- Being sick (vomiting)
- Constipation
- Upset stomach
- Back pain
- Heartbeat that you can feel (palpitations)

Uncommon side effects

May affect up to 1 in 100 people

- Fits (seizure)
- Allergic reaction (hypersensitivity)
- Worsening of nerve pain in the face (trigeminal neuralgia)
- Fast heart rate (tachycardia)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in

Ireland
HPRA Pharmacovigilance
Website: [www.hpra.ie](http://www.hpra.ie)

United Kingdom
Yellow Card Scheme
Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fampyra

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month.
Store below 25°C. Store the tablets in the original packaging in order to protect from light and moisture.

If your Fampyra is supplied in bottles, only one bottle should be opened at a time. After first opening use within 7 days.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

You can get a larger print version of this leaflet by calling the local representatives (see list below).

What Fampyra contains

- The active substance is fampridine.
- Each prolonged-release tablet contains 10 mg of fampridine
- The other ingredients are:
  - Tablet core: hypromellose, microcrystalline cellulose, silica colloidal anhydrous, magnesium stearate; film coat: hypromellose, titanium dioxide (E-171), polyethylene glycol 400

What Fampyra looks like and contents of the pack

Fampyra is an off-white, film coated, oval biconvex 13 x 8 mm prolonged-release tablet with A10 on one side.

Fampyra is supplied in either blister packs or bottles.

Bottles

Fampyra comes in HDPE (high-density polyethylene) bottles. Each bottle contains 14 tablets and a silica gel desiccant. Each pack contains 28 tablets (2 bottles) or 56 tablets (4 bottles).

Blister packs

Fampyra comes in foil blisters of 14 tablets each. Each pack contains 28 tablets (2 blisters) or 56 tablets (4 blisters).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Biogen Netherlands B.V.
Prins Mauritslaan 13
1171 LP Badhoevedorp
The Netherlands

Manufacturer:

Alkermes Pharma Ireland Ltd, Monksland, Athlone, Co. Westmeath, Ireland
For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

<table>
<thead>
<tr>
<th>Country</th>
<th>Contact Information</th>
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| België/Belgique/Belgien | Biogen Belgium N.V./S.A.  
Tél/Tel: +32 2 219 12 18 |
| България         | ТН ЕВОФАРМА  
Тел.: +359 2 962 12 00 |
| Česká republika | Biogen (Czech Republic) s.r.o.  
Tel: +420 255 706 200 |
| Danmark         | Biogen (Denmark) A/S  
Tlf: +45 77 41 57 57 |
| Deutschand      | Biogen GmbH  
Tel: +49 (0) 89 99 6170 |
| Eesti           | UAB "JOHNSON & JOHNSON" Eesti filiaal  
Tel: +372 617 7410 |
| Ελλάδα          | Genesis Pharma SA  
Τηλ: +30 210 8771500 |
| España          | Biogen Spain SL  
Tel: +34 91 310 7110 |
| France          | Biogen France SAS  
Tél: +33 (0)1 41 37 95 95 |
| Hrvatska        | Medis Adria d.o.o.  
Tel: +385 (0) 1 230 34 46 |
| Ireland         | Biogen Idec (Ireland) Ltd.  
Tel: +353 (0)1 463 7799 |
| Ísland          | Icepharma hf  
Sími: +354 540 8000 |
| Italia          | Biogen Italia s.r.l.  
Tel: +39 02 584 9901 |
| Lietuva         | UAB "JOHNSON & JOHNSON"  
Tel: +37 0 5 278 68 88 |
| Luxembourg      | Biogen Belgium N.V./S.A.  
Tél/Tel: +32 2 219 12 18 |
| Magyarország    | Biogen Hungary Kft.  
Tel.: +36 (1) 899 9883 |
| Malta           | Pharma MT limited  
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| România         | Johnson & Johnson Romania S.R.L.  
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| Slovenija       | Biogen Pharma d.o.o.  
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| Slovenská republika | Biogen Slovakia s.r.o.  
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| Suomi/Finland   | Biogen Finland Oy  
Puh/Tel: +358 207 401 200 |
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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.