

Package leaflet: information for the user

Fampyra 10mg prolonged-release tablets fampridine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Fampyra is and what it is used for
2. What you need to know before you take Fampyra
3. How to take Fampyra
4. Possible side effects
5. How to store Fampyra
6. Contents of the pack and other information

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 your doctor or nurse has told you that you have moderate or severe **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*).
- If you have been told by a doctor that you have mild problems with your kidneys

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.

Elderly

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, propranolol 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*), dizziness, 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
- Spinning sensation (*vertigo*)
- 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:

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

United Kingdom

Yellow Card Scheme

Website: 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:

België/Belgique/Belgien

Biogen Belgium N.V./S.A.
Tél/Tel: +32 2 219 12 18

България

ТП 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

Deutschland

Biogen GmbH
Tel: +49 (0) 89 99 6170

Eesti

Biogen Estonia OÜ
Tel: +372 618 9551

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

Biogen Pharma d.o.o.
Tel: +385 (0) 1 775 73 22

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

Biogen Lithuania UAB
Tel: +37 0 5 259 6176

Luxembourg/Luxemburg

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
Tel: +356 213 37008/9

Nederland

Biogen Netherlands B.V.
Tel: +31 20 542 2000

Norge

Biogen Norway AS
Tlf: +47 23 40 01 00

Österreich

Biogen Austria GmbH
Tel: +43 1 484 46 13

Polska

Biogen Poland Sp. z o.o.
Tel.: +48 22 351 51 00

Portugal

Biogen Portugal Sociedade Farmacêutica Unipessoal, Lda
Tel: +351 21 318 8450

România

Johnson & Johnson Romania S.R.L.
Tel: +40 21 207 18 00

Slovenija

Biogen Pharma d.o.o.
Tel: +386 1 511 02 90

Slovenská republika

Biogen Slovakia s.r.o.
Tel: +421 2 323 340 08

Suomi/Finland

Biogen Finland Oy
Puh/Tel: +358 207 401 200

Κύπρος

Genesis Pharma (Cyprus) Ltd

Τηλ: +357 22 765740

Sverige

Biogen Sweden AB

Tel: +46 8 594 113 60

Latvija

Biogen Latvia SIA

Tel: +371 68 688 158

United Kingdom

Biogen Idec Limited

Tel: +44 (0) 1628 50 1000

This leaflet was last revised in 07/2020

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.