

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.

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 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, 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 Fampyra 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.

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.

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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
- 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 Section 6 of this leaflet. By reporting side-effects you can help provide more information on the safety of this medicine.

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How to store Fampyra

Keep Fampyra out of the sight and reach of children.

Do not use Fampyra after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Store below 30°C. Store the tablets in the original bottle in order to protect from light and moisture.

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 comes in 2 HDPE (high-density polyethylene) bottles. Each bottle contains 14 tablets and a silica gel desiccant (in total there are 28 tablets in each pack).

Fampyra also comes in 4 HDPE (highdensity polyethylene) bottles. Each bottle contains 14 tablets and a silica gel desiccant (in total there are 56 tablets in each pack).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Biogen Idec Limited, Innovation House, 70 Norden Road, Maidenhead, Berkshire, SL6 4AY, United Kingdom.

Manufacturer:

Alkermes Pharma Ireland Limited, Monksland, Athlone, Co Westmeath, Ireland
Biologix FZ Co is responsible for distribution and drug safety in selected countries of the Middle East.
Biologix FZ Co
Dubai Free Zone, Road WB 21, Warehouse, C17 PO Box 54405, Al Tawar Dubai, United Arab Emirates

This leaflet was last revised in 07/2017

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu/>.

For any information about this medicinal product, please contact the local representative of the Marketing Authorization Holder: Biologix, FzCo, Dubai Free Zone, Road WB 21, warehouse C17 PO Box 54405 Al Tawwar Building, United Arab Emirates. Tel: (971) 4 299 7171

To report any side effect(s):

- **Saudi Arabia:**
The National Pharmacovigilance and Drug Safety Center (NPC):
Fax: +966112057662
Call NPC at +966-11-2038222,
Exts: 2317-2356-2340
Toll free phone: 8002490000
E-mail: npc.drug@sfda.gov.sa
Website: www.sfda.gov.sa/npc
- **UAE Ministry of Health**
Pharmacovigilance and Medical Device Section
Drug Department and Prevention
UAE MOH
Hotline : 80011111
Email : pv@moh.gov.ae
P.O. Box : 1853 Dubai UAE
- Other GCC States:
- Please contact the relevant competent authority

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not, by yourself, interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicament out of reach of Children Council of Arab Health Ministers Union of Arab Pharmacists