

Package leaflet: Information for the patient

Fampridine Mylan 10 mg 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 Fampridine Mylan is and what it is used for
2. What you need to know before you take Fampridine Mylan
3. How to take Fampridine Mylan
4. Possible side effects
5. How to store Fampridine Mylan
6. Contents of the pack and other information

1. What Fampridine Mylan is and what it is used for

Fampridine Mylan 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.

Fampridine Mylan 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.

2. What you need to know before you take Fampridine Mylan

Do not take Fampridine Mylan

- 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 Fampridine Mylan if any of these apply to you.

Warning and precautions

Talk to your doctor or pharmacist before taking Fampridine Mylan.

- if you feel aware of your heartbeat (*palpitations*)
- if you are prone to infections
- 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
- If you have a history of allergic reactions

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

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

Children and adolescents

Do not give this medicine 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 Fampridine Mylan

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

Do not take Fampridine Mylan 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.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Fampridine Mylan is not recommended during pregnancy.

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

You should not breast-feed whilst taking this medicine.

Driving and using machines

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

3. How to take Fampridine Mylan.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Fampridine Mylan 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.

Fampridine Mylan is for oral use.

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.

This medicine should be taken without food, on an empty stomach.

If your Fampridine Mylan 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 Fampridine Mylan than you should

Contact your doctor immediately if you take too many tablets.

Take the Fampridine Mylan 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 Fampridine Mylan

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 Fampridine Mylan 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 Fampridine Mylan** and see your doctor immediately.

Side effects are listed below by frequency:

Very common (may affect more than 1 in 10 people):

- Urinary tract infection

Common (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*)
- Viral infection
- Difficulty breathing (shortness of breath)
- Feeling sick (*nausea*)
- Being sick (*vomiting*)
- Constipation
- Upset stomach
- Back pain
- Heartbeat that you can feel (*palpitations*)

Uncommon (may affect up to 1 in 100 people):

- Fits (*seizure*)
- Allergic reaction (*hypersensitivity*)
- Severe allergy (*anaphylactic reaction*)
- Swelling of the face, lips, mouth or tongue (*angioedema*)
- New onset or worsening of nerve pain in the face (*trigeminal neuralgia*)
- Fast heart rate (*tachycardia*)
- Dizziness or loss of consciousness (*hypotension*)
- Rash/itchy rash (*urticaria*)
- Chest discomfort

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 www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store under “yellowcard”. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fampridine Mylan

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.

Do not store above 30°C. Store the tablets in the original package in order to protect from light and moisture.

If your Fampridine Mylan 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 wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Content of the pack and other information

What Fampridine Mylan contain

- The active substance is fampridine.
- Each prolonged-release tablet contains 10 mg fampridine.
- The other ingredients are:
Tablet core: Hypromellose, microcrystalline cellulose, colloidal silicon dioxide and magnesium stearate.
Tablet coat: Hypromellose, titanium dioxide (E171) and macrogol.

What Fampridine Mylan looks like and contents of the pack

White to off-white coloured oval shaped biconvex, film-coated tablet debossed with “C51” on one side and plain on other side. Tablet dimensions approximately 13.00 mm (length) and 8.00 mm (width).

Fampridine Mylan are available in blisters and bottles with child resistant closure and a silica gel desiccant canister.

Pack sizes:

Blisters: 10, 14, 20, 28, 30, 42, 50, 56, 60, 70, 84, 98, 100, 120 and 196 tablets.

Bottles: 14 tablets, 28 tablets (2 bottles of 14) and 56 tablets (4 bottles of 14).

Not all pack sizes may be marketed.

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