

Package leaflet: information for the user

Fampridine STADA 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 <Product name> is and what it is used for
2. What you need to know before you take <Product name>
3. How to take <Product name>
4. Possible side effects
5. How to store <Product name>
6. Contents of the pack and other information

1. What <Product name> is and what it is used for

<Product name> 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.

<Product name> 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 <Product name>

DO NOT take <Product name> if:

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

Talk to your doctor and do not take <Product name> if any of these apply to you.

Warnings and precautions

Talk to your doctor or pharmacist before taking <Product name>:

- 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, and this may result in an increased risk of falls
- if there are any factors, or you are taking any medicine which increases your risk of having a seizure
- if you have been told by a doctor that you have mild problems with your kidneys

Tell your doctor before you take <Product name> if any of these apply to you.

Children and adolescents

Do not give <Product name> 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 <Product name>

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

Do not take <Product name> 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 (e.g. carvedilol, propranolol and metformin) which may affect how your kidneys eliminate <Product name>.

<Product name> with food

<Product name> 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 <Product name>.

<Product name> is not recommended during pregnancy.

Your doctor will consider the benefit of you being treated with <Product name> against the risk to your baby.

You should not breast-feed whilst taking this medicine.

Driving and using machines

<Product name> 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 drive or use machinery.

3. How to take <Product name>

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. <Product name> 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 this period the treatment will be reassessed.

The recommended dose is

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 as this may increase your risk of side effects.

If you take more <Product name> than you should

Contact your doctor immediately if you take too many tablets.

Take the <Product name> 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 seizure. You may also notice other effects not listed here.

If you forget to take <Product name>

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 <Product name> 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 <Product name>** 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*)
- new onset or 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 Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Product name>

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 in the original package in order to protect from moisture.

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. Contents of the pack and other information

What <Product name> contains

- The active substance is fampridine.
Each prolonged-release tablet contains 10 mg of fampridine
- The other ingredients are:
Tablet core:
Hypromellose, microcrystalline
cellulose, colloid anhydrous silica
magnesium stearate

Film coat:
Hypromellose
titanium dioxide
macrogol

What <Product name> looks like and contents of the pack

<Product name> are white to off-white coloured, oval shaped film-coated approx. 13 mm x 8 mm tablets debossed with L10 on one side and plain on the other side.

They are supplied in blisters (Aluminium with desiccant/aluminium) packed in cartons containing

14 x 1 (unit-dose blister) prolonged-release tablets
28 x 1 (unit-dose blister) prolonged-release tablets
56 x 1 (unit-dose blister) prolonged-release tablets
196 x 1 (unit-dose blister) prolonged-release tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

This leaflet was last revised in 2025-03-07