Package leaflet: Information for the patient

Fampridine Teva 10 mg, tabletten met verlengde afgifte
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

[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)
- 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** [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 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 [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 which may affect how your kidneys eliminate medicines for example carvedilol, propranolol and metformin.

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

[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 start driving 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 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.

[Product name] 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.
[Product name] should be taken without food, on an empty stomach.

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 fits (*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 a double dose 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*)
- 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 blister and carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light and 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 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: Calcium hydrogen phosphate dihydrate, hypromellose, silica, colloidal anhydrous, magnesium stearate. Film-coating: hypromellose, titanium dioxide (E171) and macrogol 400.

What [Product Name] looks like and contents of the pack

The tablets are white to off-white, biconvex oval shaped film-coated prolonged-release tablets, debossed with R10 on one side and no debossing on the other side. Tablets dimensions are approximately 8 mm x 13 mm.

[Product Name] is available on blisters of 28 and 56 tablets, multipacks comprising 2 cartons, each containing 98 tablets and unit-dose blisters of 28x1 and 56x1 tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
Houder van de vergunning voor het in de handel brengen
Teva GmbH
Graf-Arco-Straße 3
89079 Ulm
Duitsland

Fabrikant
Balkanpharma-Dupnitsa AD
3 Samokovsko Shosse Str.
2600 Dupnitsa
Bulgarije

In het register ingeschreven onder
RVG 126649

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Kroatië:	Fampridin Teva
Tsjechië:	Fampridine Teva
Denemarken:	Fampridin Teva
Frankrijk:	Fampridine Teva
Duitsland:	Fampridin-ratiopharm
Litouwen:	Fampridine Teva
Nederland:	Fampridine Teva
Noorwegen:	Fampridin Teva
Polen:	Fampridine Teva
Portugal:	Fampridina Teva
Slowakije:	Fampridín Teva
Slovenië:	Fampridin Teva
Spanje:	Fampridina Teva

Deze bijsluiter is voor het laatst goedgekeurd in maart 2023.