Bijsluiter: informatie voor de gebruiker

Fampridine Sandoz 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 [Nationally completed name] is and what it is used for

[Nationally completed 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.

[Nationally completed 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.

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed 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** [Nationally completed name] if any of these apply to you.

Warnings and precautions

Talk to your doctor or pharmacist before taking [Nationally completed name]:
- 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 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 [Nationally completed name] 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 [Nationally completed name]

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

Do not take [Nationally completed 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 or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist before for advice before taking this medicine.

[Nationally completed name] is not recommended during pregnancy.

Your doctor will consider the benefit of you being treated with [Nationally completed name] against the risk to your baby.

You should not breast-feed whilst taking this medicine.

Driving and using machines

[Nationally completed name] 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 [Nationally completed name]

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

[Nationally completed 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.

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

If you take more [Nationally completed name] than you should

Contact your doctor immediately if you take too many tablets.
Take the [Nationally completed 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 [Nationally completed 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 [Nationally completed 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 [Nationally completed 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*)
- 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 side effects

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 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 [Nationally completed 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 package after EXP. The expiry date refers to the last day of that month.

Store below 25 ºC. Store in the original package in order to protect from moisture.

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

What [Nationally completed 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, silica colloidal anhydrous, magnesium stearate; Film coat: Opadry White (Hypromellose, Titanium dioxide (E 171), Macrogol)

What [Nationally completed name] looks like and contents of the pack

[Nationally completed name] is a white to off-white colored, approx. 13 mm x 8 mm, oval shaped film coated tablets debossed with “L10” on one side and plain on the other.

[Nationally completed name] comes in PA/Alu/Coex coating (modified PE, PE + dessicant, PE)//Alu blister packed in cartons containing:

14 prolonged-release tablets
28 prolonged-release tablets
56 prolonged-release tablets
98 prolonged-release tablets
196 (2x98) prolonged-release tablets

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
98 x 1 (unit-dose blister) prolonged-release tablets
196 (2x98x1) (unit-dose blister) prolonged-release tablets

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikant
Laboratorios Liconsa, SA
PI Miralcampo, Av Miralcampo 7,
Azuqueca de Henares- Guadalajara
Spanje

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1
D 39179 Barleben
Duitsland

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

Duitsland	Fampridin HEXAL 10 mg Retardtabletten
Spanje	Fampridina Sandoz 10 mg comprimidos de liberación prolongada EFG
Frankrijk	FAMPRIDINE SANDOZ LP 10 mg, comprimé à libération prolongée
Noorwegen	Fampridine Sandoz 10 mg depottablett
Oostenrijk	Fampridin Sandoz 10 mg Retardtabletten
Nederland	Fampridine Sandoz 10 mg, tabletten met verlengde afgifte

Portugal	Fampridina Sandoz
Polen	Fampridine Sandoz
Zweden	Fampridine Sandoz 10 mg depottabletter
Denemarken	Fampridine "Sandoz", depottabletter
Slowakije	Fampridine Sandoz 10 mg
Hongarije	Fampridin Sandoz 10 mg tablete s produljenim oslobadanjem
Griekenland	Fampridine/Sandoz
Tsjechië	Fampridin Sandoz
Cyprus	Fampridine Sandoz 10 mg
Finland	Fampridine Sandoz 10 mg depottabletti

Deze bijsluiter is voor het laatst goedgekeurd in maart 2024.