Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Fampyra 10 mg
Prolonged-release tablets

Active ingredient:
Each tablet contains: fampridine 10 mg

Inactive ingredients and allergens: See section 6 (Additional information).

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine.

- If you have any further questions, consult your doctor or pharmacist.
- This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Fampyra is intended to improve walking in adult patients with multiple sclerosis suffering from walking problems (EDSS 4-7).

Therapeutic group: pyridine isomer, potassium channel blocker.

In multiple sclerosis, inflammatory process destroys the protective myelin sheath around the neurons (nerve cells) leading to muscle weakness, muscle stiffness and difficulty walking. **Fampyra** belongs to a group of medicines blocking potassium channels; these medicines prevent potassium from leaving the neurons which have been damaged by multiple sclerosis, thus enabling signal passage in the neurons and allowing improvement of walking.

2. Before using this medicine:

Do not use this medicine if:

- you are **sensitive** (allergic) to fampridine or any of the other ingredients of this medicine (see section 6)
- you currently suffer or have ever suffered from **seizures**
- you suffer from **moderate to severe kidney problems**
- you are taking a medicine containing the active ingredient cimetidine
- you are taking any **other medicine containing fampridine.** This may increase your risk of serious side effects.

Special warnings about using this medicine

Before using Fampyra, tell your doctor or pharmacist if:

- you feel your heartbeats (palpitations).
- you are prone to infections.
- you need a walking aid, such as a cane, because this medicine may make you feel dizzy or unsteady, which may result in an increased risk of falls.
- you have risk factors or are taking any medicine which affects your risk of a fit (seizure).

- you have mild problems with your kidneys.

Children and adolescents
This medicine is not intended for children and adolescents below the age of 18 years. There is no information about the safety and efficacy of this medicine in children and adolescents below the age of 18 years.

Tests and follow up
In the age group – elderly
Before and during treatment with the medicine, your doctor may refer you to kidney function test.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
- 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 with a certain medicine which may affect elimination of medicines by the kidneys, such as carvedilol, propranolol and metformin.

Using Fampyra and food
The medicine should be taken without food, on an empty stomach.

Pregnancy, breastfeeding, and fertility:
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.
Do not breastfeed whilst taking this medicine.

Driving and using machines
Fampyra may affect the ability to drive or use machines, since it can cause dizziness. Make sure that you are not dizzy before driving or operating machines.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.
Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Fampyra is only available by prescription and under the supervision of doctors experienced in multiple sclerosis.
Your doctor will give you an initial prescription for 2 to 4 weeks. After 2 to 4 weeks, the treatment will be reassessed.
Only your doctor will determine your dose and how you should take this medicine. **The usual dosage is generally:**
One tablet in the morning and **one** tablet in the evening (12 hours apart). Do not take more than two
tablets per day. **You must leave a 12-hour interval** between one tablet and the next one.
- **Swallow each tablet whole,** with water.
- Do not split, crush, dissolve, suck or chew the tablet. This may increase your risk of side effects.

- If **Fampyra** is supplied in bottles, the bottle will also contain a desiccant. Leave the desiccant in the bottle, do not swallow it.

Do not exceed the recommended dose.

If you have accidentally taken a higher dose, contact your doctor immediately. Signs of overdose include sweating, tremor, confusion, memory loss and seizures. You may also notice other effects not listed below.
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately contact a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, do not take a double dose to compensate for the forgotten dose. **Always wait 12 hours** between one tablet and the next one.
Take the next dose at the usual time and consult your doctor. Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking the medicine, its beneficial effect will expire.
Non-continuous treatment may preclude obtaining the desired outcome. Prior to discontinuation, discuss the consequences with the doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. <u>Side effects</u>

Like with all medicines, using **Fampyra** may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.
Stop taking this medicine and consult your doctor immediately if you experience seizures or any of the following signs of hypersensitivity: swollen face, mouth, lips, throat or tongue; reddening or tingling of the skin, chest tightness or difficulty breathing.

Very common side effects (affect more than 1 in 10 users):
- Urinary tract infection

Common side effects (affect 1-10 in 100 users):
- Feeling unsteady
- Dizziness
- Spinning sensation (vertigo)
- Headache
- Feeling weak and tired
- Difficulty sleeping
- Anxiety
- Minor tremor
- Numbness or tingling of skin
- Sore throat
- Common cold
- Flu
- Difficulty breathing
- Nausea

- Vomiting
- Constipation
- Upset stomach
- Back pain
- Heartbeat that you can feel (palpitations)

Uncommon side effects (affect 1-10 in 1000 users):
- Seizures
- Hypersensitivity (allergy)
- Worsening of neural pain in the face (trigeminal neuralgia)
- Fast heart rate (tachycardia)

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! To avoid poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package/bottle/carton/label. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25˚C.
- Store in the original package to protect from light.
- For the bottle pack - After first opening, use within 7 days
- Open one bottle each time.
- Do not throw away any/the medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

- In addition to the active ingredient, this medicine also contains:
  Hydroxypropyl methylcellulose, microcrystalline cellulose, colloidal silicon dioxide anhydrous, magnesium stearate.
  Tablet coating: opadry white Y-1-7000

- What the medicine looks like and contents of the pack:
  Fampyra is a prolonged-release film-coated off-white oval-shaped (8x13 mm) biconvex tablet, with "A10" written on one side.
  Fampyra is supplied in bottle or blister packs:
  - A pack containing 56 tablets in 4 bottles containing 14 tablets each and a desiccant in plastic package – do not swallow!
  - A pack containing 28 tablets in 2 blisters containing 14 tablets each
  - A pack containing 56 tablets in 4 blisters containing 14 tablets each

Not all pack sizes may be marketed.

Registration holder's name and address:
Medison Pharma Ltd.,
10 Hashiloach St., POB 7090 Petach Tikva, Israel

Manufacturer's name and address:
Biogen Netherlands B.V., The Netherlands

This leaflet was revised in August 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 147-80-33543-00

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