The format of this leaflet was determined by the Ministry of Health and its content has been checked and approved in April 2015

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS (PREPARATIONS 1986)

This medicine will be dispensed with a physician`s prescription only

FAMPYRA® 10 mg
Prolonged-Release Tablets

Composition:
Each tablet contains:
Fampridine 10 mg
*See inactive ingredients at section 6 ("Further information") in this leaflet

Read this package insert in its entirety before using this medicine. This insert includes concise information regarding this medicine. If you have any additional questions please refer to your doctor or pharmacist.
This medicine is intended for the use of adults (over 18 years of age).

This medicine was prescribed for the treatment of your ailment, do not pass it to others as it may harm them even if they seem to have a similar disease.

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INTRODUCTION:

In multiple sclerosis an inflamatory process destroys the myelin layer arround the neurons (nerve cells) leading to muscle weakness, rigidity and walking difficulties. **FAMPYRA®** belongs to a group of therapeutic drugs which block potassium channels, these drugs prevent potassium from exiting the neurons that were damaged from multiple sclerosis, thereby improving the passage of neuronal signals enabling improvement in walking.

What is FAMPYRA® used for?
FAMPYRA® is used to improve walking in patients with multiple sclerosis (MS) who are suffering from difficulties in walking (EDSS 4-7)

Therapeutic group: Pyridine's isomer, Potassium channel blocker.

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BEFORE USING FAMPYRA®:

X Do not use this medicine if:

- You are suffering from kidney function problems
- You are suffering or have previously suffered from seizures
- You are being treated with combined therapy of other medicines containing fampridine (the active ingredient of **FAMPYRA®**)
- You are being treated with a medicine that contains the active ingredient cimetidine
- You are sensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine

! Special warnings related to the use of this medicine:
- **FAMPYRA®** is eliminated from the body by the kidneys, it is therefore recommended to perform a renal function assessment test, especially in elderly patients who may have decreased renal function
- If you are using a walking stick or a similar aid, continue using it. You may feel dizzy or unstable during the first 4-8 weeks of treatment
- **Before treatment with FAMPYRA®, tell your doctor if:**
  - o You are pregnant or breast feeding
  - o You are suffering from the following conditions:
    - ▪ Heart and/ or vascular (heart conduction problems). Irregular heartbeat
    - ▪ Kidney/ urinary system problems
- If you tend to suffer from infections
- If you have risk factors or if you are taking medicines that may effect your chances of experiencing seizures

Use in Children – FAMPYRA® must not be used in children and adolescents under the age of 18.

If you are taking or have recently taken other medicines, including nonprescription medications and food supplements, inform your doctor or pharmacist. It is particularly important to inform your doctor or pharmacist if you are taking:
- Other medicines that contain fampridine (see under "Do not use this medicine if"), drugs that are eliminated by the kidneys, such as carvedilol, propanolol and metformin

Taking FAMPYRA® with food:
This medicine must be taken without food, on an empty stomach.

Pregnancy and breast feeding:
Do not use **FAMPYRA®** if you are pregnant or breast feeding. Consult your doctor if you are planning to become pregnant.

Driving and operating machinery:
Make sure that you are not experiencing dizziness before driving or operating machinery (see section 4 "**Possible side effects**").

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HOW TO USE THIS MEDICINE?

Always use this medicine according to physician`s instructions. Check with your doctor or pharmacist if you are unsure.
- **The usual dose** is one tablet every 12 hours. Make sure that there is a gap of 12 hours between one tablet and the next. Do not exceed the recommended dose
- Swallow this medicine whole with water
- Do not suck, chew, divide, crush or dissolve this medicine as the active ingredient must be released from the tablet in a prolonged fashion (this tablet is of the prolonged-release kind)
- The package of this medicine contains a desiccant in a plastic package. Do not swallow it! Leave it in the bottle
- After two weeks of treatment your doctor will reassess the effectiveness of the treatment for you

Tests and follow ups:
You may be referred by your doctor to perform a kidney function test, before and during treatment with this medicine.

If you have accidentally taken a higher dose, you must refer to receive medical treatment at once. The signs of overdose include: sweating, tremor, confusion, memory loss and seizures.
If you have taken an overdose or if a child has accidentally swallowed from this medicine, refer to a doctor or to a hospital`s emergency room and bring the package of this medicine with you.

If you forgot to take this medicine at the specified time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Always persist with the treatment as was recommended to you by your doctor.
Even if you feel improvement in your health, do not stop treatment with this medicine without consulting your doctor or pharmacist.

If you stop taking this medicine its beneficial effect will stop.
Nonconsecutive treatment may not result in the desired effect.

If you have further questions regarding the use of this medicine consult your physician or pharmacist.

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POSSIBLE SIDE EFFECTS:

Like all medicines, using **FAMPYRA®** may cause side effects in some patients. Do not be alarmed from the list of side effects; you may not experience any of them.
You must stop treatment and refer to your doctor at once, if you suffer from seizures or if you suffer from one or more of the following symptoms of hypersensitivity: swelling of the face, mouth, lips, throat, or tongue; redness or itching of the skin; chest tightness or breathing difficulties.

Additional side effects:
Very common side effects- urinary tract infection.
Common side effects- sleeping difficulties, anxiety, dizziness, headache, feeling unsteady, numbness, tremor, shortness of breath, sore throat, feeling sick (nausea), being sick (vomiting), constipation, digestive difficulties, back pain, feeling weak and tired.
Uncommon side effects- seizures, hypersensitivity (allergy), exacerbation of face nerve pain (trigeminal neuralgia).

Consult your physician if one of the side effects worsens or if you suffer from side effects that have not been mentioned in this leaflet.

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HOW TO STORE THIS MEDICINE:

- Avoid poisoning! This medicine and all other medicines must be stored in a safe place out of the reach of children and/or infants. This will help avoid poisoning. Do not induce vomiting without being explicitly instructed to do so by your physician
- Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear eye glasses if you need them
- Do not use this medicine after the expiry date (exp. date) which appears 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
- Bottle package- use within seven days from the time the bottle has been opened

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FURTHER INFORMATION:

- In addition to the active ingredient this medicine also contains:

Microcrystalline cellulose, hydroxypropyl methylcellulose, colloidal silicon dioxide anhydrous, magnesium stearate, opadry white Y-1-7000
- What does this medicine look like and what does the package contain: prolonged-release tablets, off-white color and oval shaped with "A10" marked on one side.

FAMPYRA® comes in bottles or blister packs:
- o Package of 56 tablets, has 4 bottles, each containing 14 tablets, as well as a desiccant in a plastic package –not to be swallowed!
- o Package of 28 tablets, has 2 blisters, each containing 14 tablets
- o Package of 56 tablets, has 4 blisters, each containing 14 tablets

Not all pack sizes may be marketed.
- Registration holder and address: Medison Pharma LTD, 10 Hashiloach st. P.O.B 7090, Petach Tikva
- Manufacturer and address: Biogen Idec LTD, UK
- The content of this leaflet was checked and approved by the Ministry of Health in: 04/2015
- Registration number in the Ministry of health`s national book of drugs: 147-80-33543-00

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