

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

The medicine is dispensed with a doctor's prescription only

# Fampridine Teva

## Prolonged-release tablets

### Composition

Each tablet contains:

Fampridine 10 mg

For information regarding inactive ingredients and allergens, see section 6 – “Additional information”.

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

## **1. WHAT IS THE MEDICINE INTENDED FOR?**

Fampridine Teva is intended to improve walking in adults with multiple sclerosis who are suffering from walking problems (EDSS 4-7).

### **Therapeutic class:**

Pyridine isomer, potassium channel blocker.

In multiple sclerosis, an inflammatory process destroys the protective myelin sheath around the neurons (nerve cells) and leads to muscle weakness, muscle stiffness and difficulty walking. Fampridine Teva belongs to a group of medicines that block potassium channels. These medicines prevent potassium from leaving the neurons which have been damaged by sclerosis, thus enabling signal passage in the neurons and allowing improvement in walking.

## **2. BEFORE USING THE MEDICINE**

### **Do not use the medicine if:**

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (see section 6 – “Additional information”).
- You currently suffer or have suffered in the past from seizures.
- You suffer from moderate to severe kidney problems.
- You are taking a medicine that contains the active ingredient cimetidine.
- You are taking another medicine containing fampridine, which may increase your risk of serious side effects.

### **Special warnings regarding the use of the medicine: Before treatment with Fampridine Teva, inform the doctor or pharmacist if:**

- You feel heartbeats (palpitations).
- You are prone to suffering from infections.
- You need a walking aid, such as a cane, as this medicine may make you feel dizzy or unsteady, which may increase the risk of falls.
- You have risk factors or are taking a medicine that affects your risk of a fit (seizure).
- You have mild problems with kidney function.

### **Children and adolescents**

The medicine is not intended for children and adolescents under the age of 18 years.

No information is available regarding the safety and efficacy of using the medicine in children and adolescents under the age of 18.

### **Tests and follow-up**

#### **In the elderly age group**

Before and while using the medicine, the doctor may refer you for a kidney function test.

### **Drug interactions**

**If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.** Especially if you are taking:

- Another medicine that contains fampridine.
- Other medicines that affect the kidneys. Your doctor will exercise caution when fampridine is given at the same time as certain medicines that may affect the elimination of medicines by the kidneys, such as carvedilol, propranolol and metformin.

### **Use of the medicine and food**

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

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or planning to become pregnant, tell the doctor before using Fampridine Teva. Fampridine Teva is not recommended for use during pregnancy.

The doctor will consider the benefit of treatment with Fampridine Teva against the risk to your baby.

Do not breastfeed while using the medicine.

### **Driving and operating machinery**

Fampridine Teva may have an effect on the ability to drive or operate machinery, as the medicine may cause dizziness. Make sure you do not suffer from dizziness before driving or operating machinery.

## **3. HOW SHOULD YOU USE THE MEDICINE?**

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

Fampridine Teva is given only by prescription and under the supervision of doctors experienced in multiple sclerosis.

The doctor will initially give you a prescription for 2 to 4 weeks. After 2 to 4 weeks, the treatment will be reassessed.

The dosage and treatment regimen will be determined only by the doctor. **The generally accepted dosage is: 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.

- Swallow the tablet whole with water.
- Do not halve, crush, dissolve, suck or chew the tablet, as this may increase the risk of side effects.

- **Do not exceed the recommended dose.**

**If you accidentally took a higher dosage** refer to the doctor immediately. The signs of an overdose include: sweating, tremors, confusion, memory loss and convulsions. You may also notice other effects not mentioned here.

**If you took an overdose or if a child accidentally swallowed this medicine,** refer immediately to a hospital emergency room and take the package of the medicine with you.

**If you forgot to take this medicine at the required time,** do not take a double dose to compensate for the forgotten dose. **Always wait 12 hours** between taking one tablet and the next one. Take the next dose at the

usual time and consult a doctor. Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.

**If you stop taking the medicine, its beneficial effect will wear off.**

Non-continuous treatment may preclude obtaining the desired result. Before discontinuing the treatment you should discuss the consequences with the doctor.

**Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.**

**If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.**

## **4. SIDE EFFECTS**

**As with any medicine, using Fampridine Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects, you may not experience any of them.**

**Discontinue use and refer to the doctor immediately, if you suffer from seizures or if you suffer from one or more of the following signs of hypersensitivity: swelling of the face, mouth, lips, throat or tongue; reddening or tingling of the skin; chest tightness or breathing difficulties.**

**Very common side effects** (effects that occur in more than 1 user out of 10):

- Urinary tract infection

**Common side effects** (effects that occur in 1-10 users out of 100):

- Feeling unsteady
- Dizziness
- Spinning dizziness (vertigo)
- Headache
- Weakness and tiredness
- Sleeping difficulties
- Anxiety
- Mild tremor
- Numbness or tingling of the skin
- Sore throat
- Common cold
- Influenza
- Difficulty breathing
- Nausea
- Vomiting
- Constipation
- Digestive difficulties
- Back pain
- Heartbeats that you can feel (palpitations)

**Uncommon side effects** (effects that occur in 1-10 users out of 1,000):

- Convulsions
- Hypersensitivity (allergy)
- Worsening of nerve pain in the face (trigeminal neuralgia)
- Fast heartbeat (tachycardia)

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.**

### **Reporting side effects**

Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

## **5. HOW TO STORE THE MEDICINE?**

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

- **Store below 25°C.**

- **Keep in the original package to protect from light and humidity.**

- Do not discard medicines in the wastewater or domestic trash. Ask your pharmacist how to discard medicines you no longer use. These measures will help protect the environment.

## **6. ADDITIONAL INFORMATION:**

**In addition to the active ingredient, the medicine also contains:**

Hypromellose, Calcium Hydrogen Phosphate Dihydrate, Magnesium Stearate, Colloidal Anhydrous Silica.

### **Tablet coating:**

**Opadry Y-1-7000 contains:**

Hydroxypropyl Methyl Cellulose/Hypromellose 2910 5mPas (E464), Titanium Dioxide (E171), Macrogol (Polyethylene Glycol) 400 (E1521).

**What does the medicine look like and what are the contents of the package?**

Fampridine Teva is a white to off-white, biconvex oval shaped film-coated prolonged-release tablet, debossed with "R10" on one side.

Package sizes: 28 or 56 tablets packed in blisters (trays). Not all package sizes may be marketed.

**Name and address of the manufacturer and license holder:**

Teva Israel Ltd.

124 Dvora HaNevi'a St., Tel Aviv 6944020

The leaflet was revised in September 2023 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 174-44-37498-99

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