

## Package leaflet: information for the user

### Pristep 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 Pristep is and what it is used for
2. What you need to know before you take Pristep
3. How to take Pristep
4. Possible side effects
5. How to store Pristep
6. Contents of the pack and other information

#### **1. What Pristep is and what it is used for**

Pristep 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.

Pristep 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 Pristep**

##### **Do not take Pristep:**

- 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 Pristep** if any of these apply to you.

## **Warnings and precautions**

Talk to your doctor or pharmacist before taking Pristep:

- 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 Pristep if any of these apply to you.

## **Children and in adolescents**

Do not give Pristep 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 Pristep**

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

**Do not take Pristep 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.

## **Pristep with food and drink**

Pristep should be taken without food, on an empty stomach.

## **Pregnancy and breast-feeding**

**If you are pregnant**, or are planning to become pregnant, **tell your doctor before** you take Pristep

Pristep is not recommended during pregnancy.

Your doctor will consider the benefit of you being treated with Pristep against the risk to your baby.

**You should not breast-feed** whilst taking this medicine.

## **Driving and using machines**

Pristep 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 Pristep

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

**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.

#### If you take more Pristep than you should

**Contact your doctor immediately** if you take too many tablets.

Take the Pristep 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 Pristep

**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 Pristep** 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 Pristep** 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 Pristep**

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 packaging after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Pristep contains

- **The active substance** is fampridine.

Each prolonged-release tablet contains 10 mg of fampridine

- **The other ingredients** are:

Tablet core: hypromellose (E464), microcrystalline cellulose (E460), silica colloidal anhydrous, magnesium stearate (E470b);

Film coating: Hypromellose (E464), titanium dioxide (E171), Macrogol 400 (E1521)

### What Pristep looks like and contents of the pack

Pristep is a white to off white, oval shaped, biconvex, bevel-edged, film coated tablets, approximately 13.1 x 8.1 mm in dimensions, debossed with “FH6” on one side and plain on the other side.

#### Blisters

Pristep is supplied in foil blister packs containing 28 prolonged-release tablets, 56 tablets prolonged-release or 60 tablets prolonged-release.

Not all pack sizes may be marketed.

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

#### Vergunninghouder:

Rafarm S.A.  
Korinthou 12  
154 51 Neo Psichiko  
Griekenland  
Tel.: +30 2106776550-1

#### Fabrikant:

Pharmadox Healthcare Limited  
KW20A Kordin Industrial Park  
PLA 3000 Paola  
Malta

Rafarm S.A.  
Thesi Pousi Xatzi Agiou Louka  
190 02 Paiania  
Griekenland

### In het register ingeschreven onder RVG 132799

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

Greece: PRISTEP

**Deze bijsluiter is voor het laatst goedgekeurd in april 2025.**